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C&D

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Shipman Inquiry proposes CD reforms

by Gary Paragpuri
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The inquiry into serial killer Harold Shipman has recommended over 30 changes to the way Controlled Drugs are used in the community, in its fourth report published last Thursday.

Although Dame Janet Smith, chairman of the Shipman Inquiry, said there was no easy way to prevent a doctor from obtaining illicit CD supplies, she proposed changes to the inspection, prescribing, handling and safekeeping of CDs, to try to minimise the chances of another 'Shipman' (*see pages 11 – 13 for full recommendations*).

The changes, which will impact directly on pharmacists, include: the use of running balances for CD registers; a requirement for pharmacists to record the identity of the person collecting the CDs; the validity of CD prescriptions to be limited to 28 days; allowing pharmacists to exercise professional responsibility to dispense CD prescriptions that do not comply fully with legal requirements without referring back to the prescriber; and the use of a special form for both NHS and private CD prescriptions.

Dame Janet highlighted how easily health professionals and patients could appropriate CDs and, in particular, centred on Harold Shipman's "abnormal" prescribing of diamorphine in 1993. She criticised Ghislaine Brant, the pharmacist in charge of the pharmacy adjacent to Shipman's surgery, for failing to notice Shipman's unusual prescribing pattern.

In a six-month period in 1993, Shipman obtained 14 single diamorphine 30mg ampoules by prescribing them in the names of 13 different patients. Dame Janet said a CD register would be expected to show diamorphine prescribed by a GP for a single patient over a period of days or weeks, with the amounts prescribed becoming increasingly large and of higher doses and then stopping abruptly with the patient's death. Dame Janet argued that 12 consecutive entries for single ampoules of diamorphine 30mg were "most unusual". It was too high a dose for relief of pain from heart attacks and it was too little for chronic cancer pain but, as a single dose to a 'morphine-naïve' patient, it would be fatal, she said.

Somerford Trust was the setting for the publication of the Shipman Inquiry's fourth report last Thursday

Although Mrs Brant accepted it was her duty to ensure drugs were prescribed in appropriate doses, Dame Janet said Mrs Brant had "plainly not applied her mind to those issues" when dispensing the diamorphine to Shipman. However, in Mrs Brant's defence, Dame Janet said Shipman was an "accomplished liar" who had "deliberately set out to win her confidence and to deceive her".

Reaction

United Co-op, Mrs Brant's employer, said she was a "conscientious and experienced pharmacist" and her careful record keeping and evidence had been instrumental in his conviction. But it added: "We accept, with the benefit of hindsight, that there are lessons to be learned."

Dame Janet has told the Government that there had been "virtually no revision" to CD legislation for over 30 years. "Some of the existing provisions are sound in principle but others are out of date or have become over-complicated. In particular, many of the existing rules prevent the proper and sensible use of computer technology. It is time for revision," she said.

Ghislaine Brant was found guilty of failing to report Shipman's unusual prescribing pattern

RPSGB fitness to practise and legal affairs director Mandie Lavin welcomed Dame Janet's recommendations as comprehensive and balanced but suggested that Mrs Brant may face further investigation by the Society. "We are considering the content of the report with regard to the individual pharmacist as named in the public domain and clearly we're going to have to scrutinise and consider that in the context of our regulatory jurisdiction," she said.

Ms Lavin added that the Society would make a formal response to the report and see what practice guidance it could provide to pharmacists. "We can already see that some areas of Dame Janet's recommendations may require further practice guidance; it may well be that we've got to make amendments to our Code of Ethics...

"We've also got to have some discussions with key stakeholders and a very good example of where that needs to happen is on the whole area of running balances," she said.

"We don't want to inject bureaucracy into community pharmacy for the sake of it. We want to ensure that any solutions we come up with are pragmatic and workable, are in the interests of patients and can be operated safely and efficiently by pharmacists."

Ms Lavin also highlighted Dame Janet's recommendation that pharmacists should give patients or their representatives a proper and accurate description o the CDs prescribed. "At the moment, I think if many community pharmacists went down that route in the way that [Dame Janet] describes, they could potentially find themselves in breach of the Code of Ethics [over] patient confidentiality."

Asked what pharmacists should do now, Ms Lavin said it was a good moment to heighten awareness about professional accountability. "If it's the momen that compels pharmacists to go looking for their *Code of Ethics* and their *Medicines, Ethics and Practice Guide*, that's got to be a good thing and I think if I was a community pharmacist that's what I'd do," she said.

Home Office minister Caroline Flint said the Government accepted that it could do more to deter and detect improper use of CDs and was "determined to ensure that all reasonable measures are taken".

PSNC said it would work with the DoH to ensure the new pharmacy contract incorporated the necessary safeguards. NPA chief executive John D'Arcy said lessons needed to be learned and the NPA would seek to ensure th report's recommendations were practicable and implemented as soon as possible.

Dame Janet Smith, chairman of the Shipman Inquiry [illegible] are used in the community in her latest report [illegible] (opposite); a feature on pages 11, 12 and 13 looks [illegible] Ghislaine [illegible], who [illegible] the pharmacy [illegible]

CONTRACT

DoH makes second pay offer on new contract

by Asha Fowells
afowells@cmpinformation.com

The Department of Health has made a second pay offer on the new pharmacy contract and renewed discussions with PSNC.

Refusing to disclose the size of the remuneration package offered at last Monday's meeting, PSNC chief executive Sue Sharpe said: "We have now received an offer from the Department of Health and we are discussing with them the basis of this and how the Department have used the evidence to reach this offer."

Confirming that the offer was "clearly an advance on where we were in May" (*C&D, May 22, p4*), Mrs Sharpe added that the offer had come after the announcement of Government proposals to reclaim a further

£100 million from the generics bill (*C&D, Jul 17, p4*).

Following further talks with the DoH, PSNC will consider its position at a meeting next month. Although January implementation is still possible, Mrs Sharpe said it was more likely to be April to allow time for roadshows, probably in November, followed by a contractors' ballot.

Mrs Sharpe commented: "PSNC has committed to providing the fullest possible information for contractors so they can calculate what it means to them, and that must be right."

Welcoming the news, All-Party Pharmacy Group chairman Howard Stoate said the offer appeared to address some of the patient safety concerns that could have resulted from poor funding. "I hope this will be the basis for a successful negotiating process," he added.

A DoH spokesman confirmed that an offer had been made and negotiations were under way.

- Welsh health and social services minister Jane Hutt has "firmly indicated" that Wales will not be exercising its option to opt out of the new pharmacy contract, Community Pharmacy Wales has said. The minister told CPW that she considered it to be an England and Wales contract.

For more information:
www.psnc.org.uk

CPD pilot

Nearly 200 pharmacists have registered to participate in Northern Ireland's CPD pilot starting in September.

A new portfolio and online recording facility are being developed to support the project. In addition, a network of local facilitators will be established to help and advise pharmacists.

Running until February 2005, the pilot will be adjusted according to feedback from participants and facilitators. The refined CPD programme will be rolled out to all pharmacists in Northern Ireland by June 2005.

- The Northern Ireland Centre for Postgraduate Pharmaceutical Education and Training has introduced a course for pharmacists wishing to provide medicines management services. The first course will be on September 27 at the Fitzwilliam Hotel in Antrim.

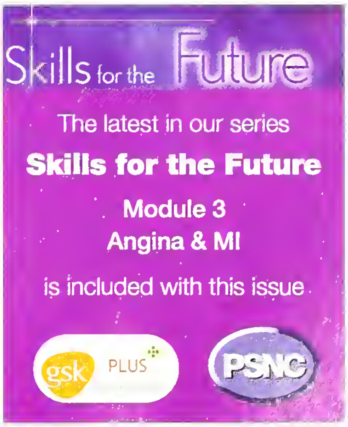
For more information:
www.nicppet.org

Pharmacist prescribing starts in NI

The first seven pharmacist supplementary prescribers have registered with the Pharmaceutical Society of Northern Ireland in the last week.

They are: Ann Burns from the Royal Group of Hospitals Trust in Belfast; Richard Clements, Carolyn Watt and Kathy Stephenson, all from Craigavon Rea Hospitals Trust in Craigavon; Fiona Roche from Sperrin & Lakeland Trust in Omagh; Barry Keenan from Sperrin & Lakeland Trust in Enniskillen; and Maureen Heatherington from the Mid-Ulster Hospital in Magherafelt.

Thirteen more hospital pharmacists have successfully completed the supplementary prescribing course and are due to register with PSNI shortly.



More info is needed on new contract, say PCTs

by Asha Fowells
afowells@cmpinformation.com

PCTs need more information on the new pharmacy contract, particularly with regards to timescale and finance, an NHS Confederation survey has shown.

Failure to provide this information could impose extreme pressure on PCTs when the contract is implemented. This happened recently with the GMS contract and could be avoided if communication was made a priority, the survey concluded.

Nearly 85 per cent of responding PCTs have identified an implementation lead for the pharmacy contract, with nearly 75 per cent using the same person who oversaw implementation of the new GMS contract. Over 90 per cent of respondents said they would attend an NHS Confederation community pharmacy contract conference in September and would welcome support in the form of briefings. Several respondents suggested that networks were formed to share good practice.

However, the survey found that less than a third of responding PCTs were aware of a strategic health authority-wide collaboration for implementing the new contract, and nearly half have a community pharmacy strategy. Two thirds of respondents said their PCT had a pharmacist on the professional executive committee.

The Department of Health has established a communications group with representatives from PSNC, the NHS Confederation and the NHS Modernisation Agency. An NHS Confederation spokesman said: "The Communications Group is aiming to enable effective two-way communication with key stakeholders to support delivery of the pharmacy contract. This will include providing information for patients and the public regarding the change."

For more information:
www.nhsconfed.org

POLICY

New name for CRHP

The Council for the Regulation of Healthcare Professionals has changed its name to the Council for Healthcare Regulatory Excellence with immediate effect.

The name change "better reflects the role and purpose of the UK-wide organisation and avoids possible confusion with bodies of similar name", CRHE has said.

Council chair Jane Wesson said: "We have agreed that we should now be known as the Council for Healthcare Regulatory Excellence because this name describes more accurately what we are here to do.

"One of our key aims is to work with the nine statutory regulators of healthcare professionals in the UK to promote excellence in regulation, building on the good work and development already being undertaken by the regulator individually.

WALES

Help with medicines management

Advice on how to get more involved in medicines management appears in a briefing paper from the Royal Pharmaceutical Society's Welsh Executive. The paper aims to act as a spur to pharmacists who might find the initial engagement daunting.

Pharmacy involvement in medicines management across Wales also outlines what is happening elsewhere in the UK.

For more information:
www.rpsgb.org/wales
Tel: 029 2041 2800

Assembly explains free script delay

The Welsh Assembly has changed its reason for taking four years to abolish all prescription charges.

After initially saying that a lack of money was the reason for refusing to scrap the charge in one go the Assembly is now blaming [illegible] administrative complications.

[illegible] says a crawl through legislation has to be initiated to draw [illegible] charge because the legal basis [illegible] patients obtain their p[illegible] will be different [illegible] of the Welsh-English [illegible]

An exp[illegible] – including pharmacists – has been set up to consider all ramifications, and it is taking the opportunity to examine issues such as whether Welsh pharmacists should directly supply over the counter medicines.

The Assembly passed a statutory instrument reducing the prescription charge from October 1 by £1 to £5 per item.

Labour initiated the proposal in its manifesto for last June's election, which saw the Party gain two seats to win a wafer-thin majority.

The issue remains controversial in Wales, with the Conservatives arguing a new community hospital could be built each year to help overcome the problem of waiting lists which are not declining as fast as across the border.

David Melding, Tory chairman of the health committee, said the total cost of abolishing charges would be nearly £50 million.

He said: "We are trying to improve intermediate care, and we could have one community hospital each and every year, instead of moving resources from relatively poor people to those who are better off."

WALES

Terms agreed for PSNC Ltd

PSNC has agreed the terms of its articles of association ahead of the organisation becoming a limited company. The committee is now looking at the rules that will govern how it runs its internal affairs, and will discuss these at PSNC's September meeting.

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gsk GlaxoSmithKline Consumer Healthcare

References:
1. Spruance SL *et al.* Antimicrob Agents Chemother 2002; **46**(7):2238-43. 2. Spruance SL. Seminars in Dermatology 1992; **11**(3): 200-206. 3. Van Vloten WA *et al.* J Antimicrob Chemother 1983; **12**(Suppl B): 89-93. 4. Fiddian AP et al. Br Med J 1983; **286**: 1699-1701. 5. Data on file, GlaxoSmithKline, 2001.

RPSGB will raise violence issue with Government

The RPSGB has promised to make the Government aware of violence against community pharmacists in light of a large rise in NHS security incidences.

RPSGB president Nick Wood, speaking in response to Prime Minister Tony's Blair's announcement on the Government's "zero tolerance" approach to crime, said: "We shall be raising with the [health] minister how this can be brought to bear on violence and threatening behaviour towards pharmacists and their staff in pharmacies both in the community and in hospitals."

Health minister John Hutton told the House of Commons that security incidences in the NHS had risen from 106,935 in 1999-2000 to 166,667 in 2001-02.

The Society's Council had agreed to raise the issue with the health minister and the Home Office at its April meeting.

● Almost three quarters of health bodies in England have finalised their requirements for conflict resolution training, according to the NHS Counter Fraud and Security Management Service. The agency has trained 112 trainers who will go on to train others and a further 75 are booked in, a spokesman said. Meanwhile, Castle Training Consultants in Uttoxeter, Staffordshire, has launched a series of courses on personal safety for shop owners in the UK.

For more information:
Castle Training Consultants
Tel: 01889 566020

OLITICS

Tories plan staff cuts at the PPA

Deep cuts in staffing at the Prescription Pricing Authority as part of a switch to e-prescriptions are being planned by the Tories.

Shadow health secretary Andrew Lansley said the PPA would be part of £1.7 billion in savings on bureaucracy uncovered by the Tory review of public spending waste by business trouble-shooter David James.

He said figures for the number of prescriptions issued through community pharmacists were collated on three separate occasions: by the GP, by the pharmacists, and by the PPA.

"By 2005, there is supposed to be 50 per cent e-prescribing; by 2007 it is supposed to be 100 per cent e-prescribing. When we get t 100 per cent e-prescribing, that entry of data should happen once, not three times.

"The PPA has about 2,200 staff which is the same number as at th Department of Health. It seems to me inconceivable that there are no substantial and, I am afraid, necessary reductions in staffing to be made."

More choice for patients

Patients should have greater choice on whether to receive a medicine or not and which medicine should be prescribed.

This view is put forward in the Royal Pharmaceutical Society's response to the Department of Health's *Choosing Health? A consultation on improving people's health*. Pointing out the serious consequences of non-compliance, the Society explains the pharmacist's important role in helping patients make choices about their medicines.

For more information:
www.rpsgb.org.uk/policy/consultation responses

LEGAL

Support at disciplinary hearings

The Pharmacists' Defence Association is developing a service in which trained representatives will accompany pharmacists to employment disciplinary hearings.

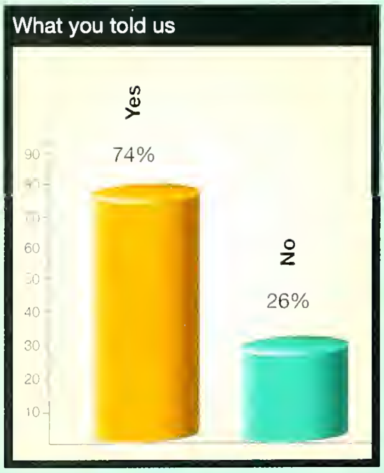
Mark Koziol, PDA director, said: "Because the PDA has now dealt with more than 300 incidents involving employment disputes since last autumn, we are attempting to establish and train a national bank of employee representatives who are prepared to support their work colleagues."

Employers are legally obliged to allow work colleagues into the disciplinary interview, said Mr Koziol. The PDA has seen cases where improper handling of the disciplinary process led to a ruling against the employer.

"Much of this could well have been avoided had appropriate support been available at the original disciplinary hearing."

Questiontime

Last week we asked you: "Is the NHS branding of community pharmacies a good idea?" You replied (see right):



This week's question: Do you approve of the RPSGB's new draft Charter?

● Yes ● No

You can record your vote on our website: *www.dotpharmacy.com*. You have until noon on July 28 to cast your vote. We will publish the results in *C&D*, July 31.

INDUSTRY

Bayer pays €2.4bn for Roche Consumer Health

by Sasa Janković
sjankovic@cmpinformation.com

Bayer has agreed to buy Roche Consumer Health for £1.59 billion, making it one of the top three over the counter consumer health companies worldwide. The acquired business has yearly sales of around £0.66bn.

Bayer also gets Roche's 50 per cent share of the 1997 Bayer/Roche joint venture in the USA, plus five Roche production sites in Grenzach, Germany; Gaillard, France; Pilar, Argentina; Casablanca, Morocco; and Jakarta, Indonesia. The OTC business of the Japanese company Chugai, in which Roche has a majority stake, is not included.

"It is our intention to further strengthen Bayer's OTC business to become world leader, and with this acquisition we make another large step towards this goal," said Werner Wenning, chairman of the board of management of Bayer AG. "Additionally, the acquired business is of high value – the combined product portfolios are very complementary and contain strong trusted brands. The acquisition also provides growth and attractive profit margins in an interesting and fast developing part of the healthcare market, one which is characterised by increasing consumer interest in overall health and self-medication. This is a good opportunity for our products."

Both companies have a number of well-known brands such as Bayer's Aspirin, Alka-Seltzer, Midol and One-A-Day and Roche's Aleve, Bepanthen, Berocca, Flanax, Redoxon, Rennie, and Supradyn.

"The new organisation will be uniquely positioned to exploit the growth potential in the OTC market and emerge as a partner of choice for future Rx/OTC switches," said Arthur Higgins, chairman of the executive committee of Bayer HealthCare.

The combined company will have sales of £1.6bn and 6,700 employees in 120 countries. It will be headed by Gary Balkema, currently president of Bayer HealthCare's global Consumer Care Division and have its global headquarters in Morristown, New Jersey, USA. The European headquarters will be in Switzerland in the Basel area. Research and development will be situated at Bayer Consumer Care headquarters in Morristown and at the Roche Consumer Health site in Gaillard, France.

For more information:
www.bayer.com

CFSMS hits back at criticism

Jim Gee, director of the NHS Counter Fraud and Security Management Service, has hit back at generics manufacturers who suggest the NHS will be the victim if 30 more investigations are made into anti-competitive behaviour (*C&D, July 3, p10*).

The CFSMS is taking further proceedings against generic manufacturers, this time over the sale and supply of ranitidine.

Responding to Paul Duke, secretary-general of the British Generic Manufacturers Association, who said nothing should distract generics companies from providing high quality, low cost medicines, Mr Gee said: "We want to work with generics manufacturers but the fact is that money has been lost by the NHS to unlawful action and the NHS is determined to get that money back."

IT

Software update

NDCHealth has added a new function called Knowledge Base to its Pharmacy Manager dispensary management software.

Currently being beta tested, Knowledge Base is included in version 5.0 of Pharmacy Manager, and contains patient education leaflets, medicines information, medical updates and a database of medical services.

For more information:
www.ndchealth.co.uk

ABPI and NHS Alliance launch framework paper

by Sasa Janković
sjankovic@cmpinformation.com

A framework to guide work between the pharmaceutical industry and the NHS has been launched by the Association of the British Pharmaceutical Industry and NHS Alliance.

The document follows a survey undertaken by Medical Management Services and supported by the ABPI showing more than half of Primary Care Organisations now work in partnership with the pharmaceutical industry.

The *ABPI Framework for Joint Working between the Pharmaceutical Industry and the NHS* is a practical guide to joint working projects, for the benefit of patients.

It outlines the principles for co-operation and lists important lessons learnt so far, as well as highlighting pointers for successful joint working relationships and case studies. A suggested framework checklist is provided to help plan, organise and implement such initiatives.

The guide stresses that all such joint activities should be for the benefit of both individual patients and for wider populations and that any agreements between the industry and NHS partners are conducted in an open and transparent manner.

"The *NHS Plan* and other recent publications from the Department of Health all point to the benefits that can come from a constructive engagement with the private sector," said Dr Trevor Jones, director-general of the ABPI.

"In the spirit of this developing relationship, the ABPI has produced this document to introduce NHS managers and decision-makers to the benefits of partnership with the pharmaceutical industry."

Michael Sobanja, chief executive of the NHS Alliance, added: "Patients benefit by close and effective working between the pharmaceutical industry and the NHS. This document sets out a framework for such partnerships and gives excellent examples of how this works in practice."

Copies of the *ABPI Framework for Joint Working between the Pharmaceutical Industry and the NHS* are available free to NHS organisations from the ABPI on 020 7930 3477 ext. 1446 or e-mail *publications@abpi.org.uk*. It is also available on *www.abpi.org.uk*.

Montpellier out of Oxford

Montpellier Group has pulled out of a deal to build a new medical research laboratory at Oxford University. It offered no reason for its decision and has not confirmed that it is due to intimidation by animal rights extremists.

However, the Association of the British Pharmaceutical Industry has branded as "appalling" the fact that animal extremists might have been able to force building contractors to withdraw from the Oxford facility.

Healthpoint hits 300

Healthpoint Technologies has sold its wound care system in the British Isles to Buckley store in Lancashire.

[illegible] managing director John [illegible] said: "Healthpoint is continually enhancing and providing state of the pharmacy primary care. We are also willing to incorporate any local information suggested by PCTs and [illegible] our database."

Health bodies link up for party conference season

Twenty seven health organisations are joining forces to promote debate at this year's party political conferences.

The Health Hotel will see the organisations hosting joint receptions at all three party conferences, as well as holding a range of fringe meetings under one roof at the Labour Party conference.

The alliance includes organisations from across the health sector, from campaign charities, patient groups and professional associations to think tanks and national NHS bodies.

Martina Bohn, project manager for the Health Hotel, said: "With health at the top of the agenda for the general election campaign, we believe the Health Hotel initiative is a great opportunity to promote new ideas and fresh thinking about the priorities for the next Government."

The Health Hotel is supported by the Health Foundation, with the Association of British Pharmaceutical Industry supporting the three joint receptions.

UniChem award

UniChem has been rewarded by Boots with a Best Collaborative Supplier Relationship award. UniChem worked with Boots's supply chains to improve levels of service and introduced a system to provide delivery solutions. David Coles, UniChem managing director, said: "This is a marvellous achievement, which recognises the efforts of everyone in the business."

Phoenix turnover up

Phoenix Pharmahandel AG & Co KG has released its results for the fiscal year 2003/2004, showing group turnover up to £10.8 billion (previous year: £10.2bn). Chairman Dr Bernd Scheifele said: "The further expansion of [our] market position was made possible through important acquisitions in Croatia and Slovakia as well as the acquisition of the minority interests in the Tamro Group."

NatraHealth is born

Chris Keeble, former sales director of Nutralife (UK) Ltd, manufacturer of the NatraHealth, NatraVits and NatraHerb brands, has led an MBO of the company's retail division and formed a new company called NatraHealth Ltd. NatraHealth keeps the original team of John Sargent as national account manager and Brian Mayor as sales manager, while Mr Keeble becomes managing director.

Boots gets made up

Cosmetics company Constance Carroll has won a major order to supply its Collection 2000 range to Boots The Chemists. The range, from lipsticks and nail varnish to eye shadow, is being introduced into 296 Boots stores nationwide over the next six months.

For excellence

Nottingham company Pharmaceutical Profiles has won Frost & Sullivan's 2004 Excellence in Technology Award in the field of drug discovery and development. The award recognised the company's efforts to enhance the adoption of innovative technologies in early phase drug development.

DepoMorphine deal

SkyePharma has entered a marketing agreement with Medeus Pharma for the marketing and distribution of DepoMorphine in Europe. DepoMorphine is SkyePharma's sustained-release injectable formulation of morphine for relief of moderate-to-severe post-operative pain.

The Shipman legacy

The Shipman Inquiry's fourth report looks at the regulation of Controlled Drugs. It is destined to have a lasting effect on pharmacy practice, reports **Gary Paragpuri**

There is no easy way to prevent a doctor who is determined to obtain illicit supplies of a Controlled Drug from doing so. Nor is there any foolproof way of detecting, after the event, that a doctor has diverted CDs to his or her own use, Dame Janet Smith, chair of the Shipman Inquiry, has concluded in her fourth and penultimate report.

Nevertheless, she proposes over 30 changes to try and minimise the risk of another 'Shipman', in her report to David Blunkett and John Reid, secretaries of state for home affairs and health.

She recommends:

- The setting up of an integrated and multidisciplinary inspectorate to monitor and audit the prescription, storage, distribution and disposal of CDs.
- The instigation of restrictions on CD prescribing to discourage or prevent health professionals from prescribing in unsafe or unwise circumstances, such as prescribing for their own or their family's use.
- The tightening up of the handling and safe keeping of CDs, along each part of the supply chain, from suppliers to patients, in order to provide a complete audit trail of CDs in both the NHS and private sector.

In making these proposals, Dame Janet says she kept in mind that the measures should not adversely affect health professionals. "Doctors who wish to prescribe CDs for the genuine needs of patients must not be unduly hindered from doing so. Pharmacists must not be over-burdened with administrative requirements when dispensing CDs."

In her 250-page-plus report, she examines in detail all aspects of CDs in primary care, from GPs' authority to prescribe, prescription requirements, through to pharmacists and the dispensing of CDs, the storage of CDs in pharmacies, the inspection of CDs and the destruction of CDs.

She highlights how easily health professionals and patients can appropriate CDs, and describes how former GP Harold Shipman manipulated the system to his benefit.

There has been virtually no revision of the legislation relating to CDs for over 30 years, Dame Janet says. Some of the existing provisions are sound in principle but others are out of date or have become over-complicated. "It is time for revision," she concludes.

A chief part of her report centres on Shipman's "abnormal" prescribing of diamorphine in 1993, and the actions of pharmacist Ghislaine Brant, who managed the pharmacy adjacent to Shipman's surgery.

Between February and August 1993, Shipman obtained 14 single diamorphine 30mg ampoules by prescribing them in the names of 13 different patients.

"The question arose," says Dame Janet, "as to whether this pattern of prescribing was so abnormal that it should have aroused the concern of the pharmacist who dispensed them, Mrs Brant, and/or that of detective constable Patrick Kelly,

Continued on page 12 ▶

the chemist inspection officer (CIO)."

CD register entries for diamorphine would be expected to show the drug prescribed by a doctor for a single patient over a period of days or weeks, Dame Janet says, with the amounts prescribed on each occasion becoming increasingly large, often culminating in supplies of as much as 10 ampoules of 100mg. Finally the supplies come to a sudden end with the patient's death.

These entries would also be expected to be interspersed with requisition orders, usually asking for boxes of five ampoules, as well as prescriptions issued by other doctors. But, according to Dame Janet, the appearance of the diamorphine section of the register at Mrs Brant's pharmacy was "most unusual".

"On one page, there appeared 12 consecutive entries, made between February and May 1993, each recording the supply of a single 30mg [diamorphine] ampoule, each prescribed by Shipman, each in the name of a different patient. On four days – two of them within the same week – Shipman had prescribed two single ampoules for different patients on the same day."

Mrs Brant told the Inquiry that Shipman collected the ampoules himself and she had not thought that there was anything suspicious about the prescriptions. Dame Janet disagrees: "A single 30mg ampoule is a very unusual amount of diamorphine to prescribe. It is far too much to administer to a patient who is suffering from the acute pain of a heart attack and too little to prescribe for a patient who has chronic pain caused by cancer. As a single dose, given to a 'morphine-naive' patient, it would be fatal."

Although Mrs Brant held Shipman in "very high regard", she should have been aware that this pattern of prescribing was "most unusual" and she should have been concerned that Shipman collected the drugs himself, Dame Janet argues.

"The question arose as to whether this pattern of prescribing was so abnormal that it should have aroused the concern of the pharmacist who dispensed them"

Dame Janet Smith

"She was not concerned because, she said, she trusted him completely and because the amount of drug collected was not so large as to give rise to the suspicion that Shipman might be addicted to diamorphine, a sign that she knew it was her duty to look out for," Dame Janet says.

While Mrs Brant accepted it was her duty to ensure that drugs were prescribed in appropriate dosages, Dame Janet said: "She had plainly not applied her mind to those issues in respect of the patients for whom Shipman had prescribed 30mg diamorphine."

Further, Dame Janet dismisses Mrs Brant's claims that, as she was supplying the drug directly to a doctor, it was reasonable for her to rely on the doctor's expertise. "I do not accept the distinction," Dame Janet says. "A pharmacist is under duty to ensure, so far as possible, that the doctor does not prescribe an excessive quantity of a Controlled Drug. The fact that the doctor is present when the drug is dispensed does not affect that duty."

Dame Janet adds that if, on enquiry by the pharmacist, the doctor says they know the prescribed quantity was greater than needed and that they intend to give only part of the dose and discard the rest, then it would be reasonable for the pharmacist to assume the doctor would give an appropriate dose.

Nevertheless, pharmacists have a duty to "prevent the supply of unnecessary and excessive quantities of medicines" and Mrs Brant should have discussed the abnormal prescribing pattern with the pharmacy superintendent, the chemist inspection officer or the RPSGB inspector, Dame Janet says.

Other than the diamorphine register entries, Dame Janet says Mrs Brant ran the pharmacy very well. "The premises were well kept; her dispensing was very efficient and there was no reason to question her managerial or professional abilities." In defence of Mrs Brant, Dame Janet says Shipman was an "accomplished liar" who had "deliberately set out to win her confidence and to deceive her".

The failure of Patrick Kelly, the CIO for Hyde, to notice anything unusual about the page of consecutive entries for single 30mg diamorphine ampoules is also highlighted in the report.

Even though he was inexperienced, he should have recognised the entries as very unusual, Dame Janet argues, but adds: "My criticism of DC Kelly is mitigated by his inexperience, by the inadequacy of his training as a CIO and by the lack of supervision from a more senior GMP officer."

The role of RPSGB inspector David Young is also scrutinised. The usual practice of RPSGB inspectors was to examine a CD register to ensure it was being kept, that entries were legible, and there were no worrying alterations, says Dame Janet. "An inspector would not be looking out for signs of irresponsible prescribing; s/he might notice such signs but, if s/he did, it would be more by luck than design."

It is not clear whether Mr Young examined the register at Mrs Brant's pharmacy during the period in question and he cannot be criticised for not doing so, Dame Janet states. Nor can the RPSGB be criticised, she says, for not requiring inspectors to pay closer attention to the content of registers. "It has never been their duty to do more than ensure that the pharmacy is being properly run and the legislation complied with."

It is hard to do justice to Dame Janet's 256-page report in a 2,000-word article. She describes the shortcomings that exist in the current system of prescribing, dispensing and monitoring CDs in the community, and suggests 33 recommendations for change in England.

On the grounds that it is reasonable to expect the Government to act on them, it would be wise for pharmacists to take the time to read the report. It can be downloaded from the Shipman Inquiry website at *www.the-shipman-inquiry.org.uk* or by calling 0161 237 2435/6.

Main points from the Shipman Report

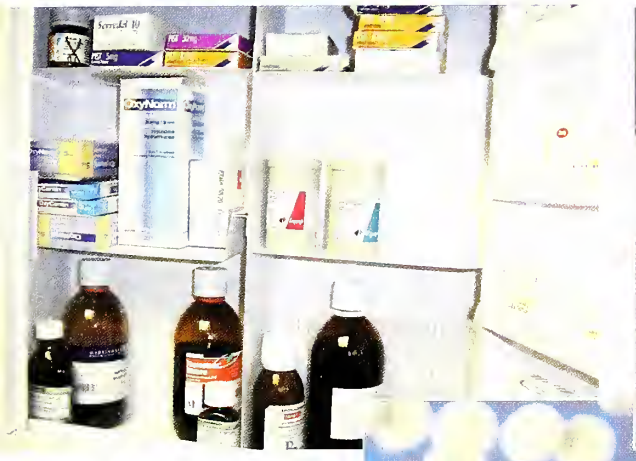
Dame Janet's fourth report for the Shipman Inquiry makes 33 recommendations for change in England and many will impact directly on pharmacy. They include:

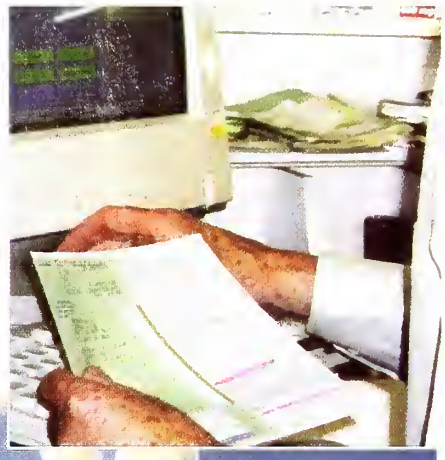
Inspections

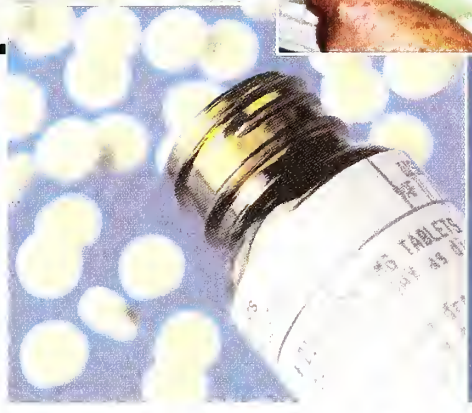
The setting up of a CD inspectorate comprising pharmacists, doctors and investigators responsible for inspecting pharmacies and surgeries to oversee safekeeping of CDs, maintenance of registers, and supervising CD destruction. The inspectorate would also monitor CD prescribing by prescription analysis and PACT data and be responsible for issuing CD prescription pads.

CDs in the pharmacy

There should be some relaxation of the requirement that a pharmacist is not permitted to dispense a CD prescription unless there is full compliance with every legal technical requirement. If the defect is only technical, and the prescriber's intention is clear and the pharmacist is willing to accept professional responsibility for the prescription, then the pharmacist should have the discretion to amend the prescription, correct







Running balances for CD registers should be regarded as good practice

the defect, and dispense it.
- Pharmacists should record in the CD register the name and address of the person collecting the drug unless the information is already known. If the person is unknown to the pharmacist, then the name, address and a note of the form of the identification produced should be recorded in the register. If no identification is produced, the pharmacist should have the discretion to supply or withhold the drug.
- A healthcare professional who presents a prescription or requisition for a CD in their professional capacity should, if unknown to the pharmacist, be required to provide identification such as their professional registration card. This should be noted in the register.
- Any person collecting CDs should write their name on the back of the prescription.
- Pharmacies should be permitted to keep electronic CD registers.
- Running balances for CD registers should be regarded as good practice and the Home Office and the RPSGB should make this clear. Running balances should be obligatory when electronic CD registers are available.
- The name and registration of the prescriber and the dispensing pharmacist should be entered in the register.
- CD registers should be kept for up to 10 years or longer if electronic.
- The RPSGB should give guidance to pharmacists as to what advice and information needs to be given to patients receiving CDs. Patients should be advised to return unused CDs.

GPs' prescribing rights

- Medical practitioners should be entitled to prescribe CDs only for the purpose of the clinical practice in which they are engaged.
- It should be a criminal offence for doctors to prescribe CDs for themselves or to self-administer CDs except in emergencies. It should be unacceptable for doctors to prescribe CDs to immediate family members.
- The Government should review and audit the way in which the GMC and PCTs use their powers to restrict the rights of doctors involved in CD offences to prescribe CDs.
- When a restriction is made to a doctor's prescribing rights, the information should be promptly made available to pharmacists.

Prescriptions

- A special form should be used for prescribing CDs, both within the NHS and the private sector.
- Prescribers should be encouraged to print the prescribing information on the form and then copy it by hand.
- The existing handwriting requirements should not be repealed until the arrangements for computer generation and transmission of CD prescriptions has been shown to be secure.
- The CD prescription forms should require the prescriber to indicate: whether the prescription is NHS or private; and a brief description of the condition for which the CD has been prescribed. Prescribers should ask patients to consent to this provision.
- Prescriptions for CDs should be limited to 28 days' supply and 28 days' validity except for Schedule 5 drugs.
- When ETP is introduced, the software should record the [illegible] issue and dispensing of the prescription.

Safe custody/record keeping for GPs

- CD prescription and requisition should be carried out using the same special forms.
- All such forms should be sent to the PPA.
- GPs who store CDs should be permitted to have an electronic CD register with running balances.

CDs in the community

- Pharmacists should be required to prepare a patient drug record card (PDRC) to accompany every supply of injectable Schedule 2 drugs.
- Health professionals who administer Schedule 2 injectable drugs must record every administration and supply of such a drug on a master PDRC, which is sent to the PCT on completion.
- Consideration should be given to changing the law so that all CDs become property of the Crown on the patient's death.
- The destruction and removal of CDs from patient's homes should be properly recorded and witnessed.

Comment from the Editor

Last week's question was: Is the NHS branding of community pharmacies a good idea?

"Yes. Using the logo in pharmacies would incorporate pharmacists as part of the NHS"

Rashmi Patel, Hillingdon

"Yes, I like it. It gives pharmacies a sense of identity"

Robert Townsend, Swindon

"I'm undecided at the moment. I haven't heard enough about it so far to decide if it is a good idea"

...n, Ramsgate

The reverberations caused by the UK's worst mass murderer, the GP Harold Shipman, are still working their way through the system.

The latest report from the Shipman Inquiry considers the way Controlled Drugs have been regulated in the past and makes many sensible suggestions for change. There will have to be more thought on the practicalities, but the document will add further impetus to the urgent need for community pharmacy IT connectivity to the rest of the NHS.

As well as her recommendations on the handling of CDs, Inquiry chairman Dame Janet Smith sets out her expectations of how a health professional should behave.

She is critical of one pharmacist beguiled by Shipman. His murderous prescribing habits were not regarded as suspicious by the pharmacist (or the drugs inspectorate). Nor did the pharmacist assert her professional identity or rights sufficiently to challenge the 'quirky' prescribing.

But this was the early 1990s before the true horror of Shipman's activities were revealed and while there was still a hierarchy in health professionals' opinions.

Attitudes and expectations have changed. The promotion of pharmacists' skills and abilities has shifted the balance in the pharmacist-GP relationship for the better, and the public's own expectations have helped empower pharmacists.

The Society and its inspectorate were not criticised particularly, but this is no reason for it not to review the inspectorate – whether in terms of size or powers. It is at times like this that the Society can show strong leadership – not only to the profession but to the world at large.

The public's own expectations and demands have helped empower pharmacists

Yourviews

Bharat Shah argues for recalibrating generics prices upwards

Generics under scrutiny

The Government has announced a proposed reduction in Drug Tariff from September this year in four products. In a way it is difficult to argue against this reduction as the Government will do it anyway.

My dissatisfaction is that the Government has not looked at the Maximum Price Scheme that it introduced in 2001 at all. Some products do need to be recalibrated up in prices. Moreover there are many products in the *Drug Tariff* that are unreasonably priced, being very low and which in reality are never available at these low prices. Pharmacists are losing money in many instances.

Bharat Shah: the Government has not looked at its own Maximum Price Scheme

Why are these not being looked at? Many products that are not available from time to time do not get into the NCSO scheme. Why is that? If gross margins of pharmacies are reduced by such clawback methods and mismanagement, I fear that the new NHS plan to have pharmacies more accessible to the public will not be a reality.

I believe that the NHS should also take more positive action in off-patent molecules such as amlodipine where they have allowed prescribing of a salt that will drain resources of NHS in the long run.

Bharat Shah is the managing director of Sigma Pharmaceuticals Plc

TOPICAL REFLECTIONS

Old money for new services

At last I can see how the new contract will be funded – from our own pockets. Lord Warner's announcement that a further £100 million will be slashed from generics payments in September paves the way for a new contract announcement in October.

Coupled with the £200m cut made last December, that's about £300m taken away from community pharmacy in 12 months. Pharmacists will bear the brunt of these cuts as there is little scope for manufacturers to cut their prices further. These savings will allow the Government to announce up to £300m of 'new' money to fund additional services. Well thanks a bunch; I will be very grateful for the return of my money.

It's no secret that we make a good proportion of our profits from generics purchasing but we work hard for this money, and it ultimately saves the NHS money by keeping generics prices low.

So it seems that we will get very little additional money for all these great services we'll be providing under the new contract. Rather, our existing remuneration is being redistributed. But the trouble is, I don't believe there's enough existing money in the pot to fund these services. How will I pay for my consultation room and locum cover to allow me to offer these services? And that's just the tip of the iceberg – there's additional training requirements for me and my staff, IT costs to enable ETP, etc.

I really don't understand why, at a time when the Government is pumping huge amounts of additional money into the NHS, pharmacy does not merit at least a small proportion of this funding. It's not as if we're asking for a straight pay rise, it's new money for new services that we want.

Please keep CD requirements sensible

I'm not really looking forward to the strieter controlled drugs requirements I expect to be forced on me by the Shipman report. And I definitely don't need any more work or red tape at a time when I'm struggling to keep up with my current workload.

There are a couple of anomalies in the current system I would be happy to see cleared up however. Care homes keep a running total of their CD stock, so perhaps we should as well. It would be easy for the odd packet to go 'missing' if a strict audit is not kept and a running total is easily done, besides being a useful stock control method. My homes also ask me to sign for their returned CDs, but no records are required for either patient-returned CDs or date expired stock. Another loophole to be closed perhaps.

Remember, remember, the Thinflex patch

I'm glad that GlaxoSmithKline is replacing its NiQuitin CQ Clear and Classic patches with just one improved product – Thinflex NiQuitin CQ. I don't stock the Classic patches because I never found anyone who preferred an opaque patch to a clear one, but it did create potential confusion.

I'm also glad that the industry is investing vast sums of money in improving the range of NRT products that I have to offer. But on this occasion I wonder whether the Thinflex offers any real advantage over the Clear patches. Of course patients want a comfortable patch, but I'm not convinced it's a good idea they completely forget they are wearing it.

Quitters who forget they are wearing a patch may not remember that they have stopped smoking before they inhale that first lungful of smoke. They may forget to be on their guard and walk into difficult situations unprepared, or lose sight of all the reasons why they want to stop. They may even apply a new patch before removing the old one.

I would have thought a gentle reminder of quitters' smoke-free status was beneficial, but patient feedback will soon tell me the answer.

Your Views

Proposals for CDs need to be workable

It is inevitable that a disaster like Shipman will raise questions about systems and processes with a view to preventing such an occurrence in the future.

While this was a horrific occurrence of unprecedented magnitude, it has to be recognised that it was also an extraordinary one-off. Consequently when considering the recommendations a sense of realistic balance must be applied.

Pharmacists are involved in a very large number of prescriptions for Controlled Drugs every year and often have to handle very difficult CD-specific situations which they routinely undertake with a high degree of skill and professional judgement, acting in the patient's interest.

Dame Janet Smith said that there was no easy way to stop a doctor determined to obtain illicit supplies of CDs. We must be sure that any changes that we now implement are not onerous to the extent that they also prevent a genuine patient from receiving their supply of essential CDs.

We will be considering the report very carefully and are keen to see that while there will now be a general tightening up of systems, it will be important for pharmacists to be able to continue to make professional judgements in the interests of patients without the fear of undue persecution.

Thought needs to be given to the pharmacist at the sharp end and the scenario where a desperate relative of a dying patient will want an unencumbered supply when they present with their CD prescription.

The PDA is keen to work with all relevant bodies to ensure that any new processes are workable for pharmacists and are truly in the interests of patients."

Mark Koziol, director, Pharmacists' Defence Association.

Wyeth

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Side effects or cancer progression? *Mary Allen* describes two case studies in which antidepressants complicated the clinical picture

SSRIs in cancer

THE COLLEGE OF PHARMACY PRACTICE
This course (module 1310), in association with multiple choice questions being published in *C&D* August 7, provides one hour's continuing education

- To be aware of starting doses of SSRIs
- To know the symptoms and risk factors for hyponatraemia
- To be aware of serotonin syndrome
- To be alert to patients receiving drugs from different prescribers
- To know when to challenge prescriptions

Patients with cancer frequently have other problems too. They often receive multi-agency care, with the different prescribers and pharmacists unaware of the whole picture. Drug side effects and interactions may not be immediately obvious as such, and may sometimes be wrongly diagnosed as symptoms related to malignancy or other illness.

Depression is common in cancer patients and the following two case studies show how anti-depressant therapy may complicate the issues.

1. Drug-induced hyponatraemia (low serum sodium)

Dorothy Newham is a small lady in her 70s. She is currently undergoing a course of chemotherapy, which she appears to be tolerating fairly well. However, a few days ago, her son visited your community pharmacy to collect Dorothy's repeat prescription and mentioned that his mother wasn't feeling very well at the moment – she seemed confused and lethargic, and generally "not herself". He wonders if the chemotherapy is taking its toll.

Her medicines

Her community pharmacy patient medication record shows prescriptions for:

Mixtard Insulin 30/70
Blood-glucose testing strips, lancets etc
Escitalopram 10mg daily, first dispensed two weeks ago
Lisinopril 10mg daily

We also know that Dorothy is undergoing chemotherapy, but do not know which regimen, or for what type of cancer. We do not know whether the escitalopram was initiated by the GP and dispensed for the first time as above, or originated by a hospital doctor and continued by the GP.

Mr Newham calls in a couple of days later for a prescription for himself and tells you that his mother has been admitted to hospital where a blood test showed that her plasma sodium levels were very low. What's going on? Is it the chemotherapy, the cancer or something else?

Hyponatraemia may result from one of various mechanisms, creating a sodium–water imbalance in the body, and in individual patients more than one factor may be involved.

One cause is the syndrome of inappropriate diuretic hormone secretion (SIADH), resulting in a dilutional hyponatraemia through excess water being retained in the body. Some cancers can cause SIADH, most commonly lung-related cancers, but the syndrome can also occur with other cancers such as those affecting the prostate or thymus. Some other medical conditions, including TB and pneumonia, can cause SIADH.

The syndrome is also associated with certain drugs including carbamazepine, vinca alkaloids (used in some chemotherapy regimes), antidepressants and some antipsychotics.

Are the drugs to blame?

We do not know what type of cancer Mrs Newham has, or whether this could cause SIADH. Nor do we know which chemotherapy drugs Mrs Newham is receiving or whether these include vinca alkaloids, which are associated with SIADH.

However, we do know that she has been taking escitalopram, a selective serotonin reuptake inhibitor (SSRI), for at least two weeks at a dose of 10mg daily.

Where several agencies are prescribing for a patient, it might be useful for information on medicines prescribed to a patient are communicated to their community pharmacy

The *British National Formulary* carries a Committee on Safety of Medicines warning about antidepressants and hyponatraemia which states: "Hyponatraemia (usually in the elderly and possibly due to inappropriate secretion of antidiuretic hormone) has been

Continued on page 18

associated with all types of antidepressants; however, it has been reported more frequently with SSRIs than with other antidepressants. The CSM has advised that hyponatraemia should be considered in all patients who develop drowsiness, confusion, or convulsions while taking an antidepressant."

What about the dose?
Is 10mg escitalopram daily appropriate for an elderly patient, either as a starting dose or for continuation?

The recommended starting dose for depression is 10mg daily, and for panic disorder 5mg increasing to 10mg daily. For the elderly, the manufacturer recommends halving these doses. So Mrs Newham's dose is too high for a starting dose and probably too high for a continuation dose too.

In Mrs Newham's case, her GP had initiated the drug and the prescription on the PMR was, in fact, the first supply so the dose was higher than recommended and put the patient at potential risk. On discussion it emerged that the GP was unaware that Cipralex (escitalopram) was an isomer of citalopram and was effectively twice as strong. A phone call from the community pharmacy to establish whether this was the first prescription or to query the dose might have helped to prevent Mrs Newham's hyponatraemia.

The risk factors
Hyponatraemia is a rare but potentially serious side effect of antidepressants. No antidepressant is known to be free of the potential for this effect. It is thought to be more likely with SSRIs but this may be a result of wider reporting of the side effects with SSRIs because the drugs are newer.

Risk factors for developing hyponatraemia with SSRIs include:
- older age
- female sex
- low body weight
- reduced renal function
- medical co-morbidity (such as hypertension, diabetes, hypothyroidism, COPD, some cancers, stroke)
- [illegible] other drugs, including diuretics, NSAIDs, carbamazepine, some chemotherapy drugs
- warfarin [illegible]

What about Mrs Newham?
Mrs Newham is a small elderly female with diabetes, so she has several known risk factors. She may also have some degree of renal impairment because of age and diabetes. Although we do not know her cancer type or the nature of her chemotherapy, these may be important additional factors. Her GP prescribed an initial dose of escitalopram that was greater than the recommended starting dose for the elderly. This was found to be the trigger for her hyponatraemia, and she recovered after discontinuing the medicine.

Treatment consists of withdrawing the SSRI and close monitoring of sodium levels. Abrupt discontinuation of SSRIs is not without problems because of the risks of discontinuation symptoms (*see C&D, Pharmacy Update, July 10*), and this will complicate the clinical picture, so close supervision is required.

What can we learn from this?
Community pharmacists should challenge first prescriptions of SSRIs and other antidepressants which appear to be in excess of recommended starting doses, especially in the elderly or in patients with other risk factors, such as those with co-morbidity or taking other drugs known to be associated with hyponatraemia.

Older patients, or others at risk, should be monitored in the early days of taking antidepressants for signs of hyponatraemia (dizziness, nausea, lethargy, confusion, cramps, seizures). GPs and other prescribing doctors may wish to monitor sodium levels in high-risk patients before commencing treatment, after two weeks, after four weeks and then every three months.

Some cancers can cause SIADH, or syndrome of inappropiate diuretic hormone secretion but it is also associated with antidepressants

Can Mrs Newham switch to another drug?
Hyponatraemia can occur with any antidepressant. Once Mrs Newham's sodium levels return to normal, doctors may wish to try treating her with a lower dose of escitalopram, carefully monitoring her sodium levels. Or, they may wish to switch her to another type of antidepressant, for example a noradrenergic type such as lofepramine, again monitoring closely. Alternatively, her depression may be helped by non-pharmacological methods and psychological support. If her depression is severe she may, at least in theory, benefit from ECT, although it is unlikely that this would be a course of action for this relatively frail patient.

2. Serotonin syndrome

John Parkinson is a cancer patient in his 40s. His illness is advanced. He is undergoing some chemotherapy to alleviate some symptoms and his pain has been well controlled on morphine for some time. Over the last year you have dispensed controlled-release and immediate-release morphine in increasing doses for John, and for the last eight months you have dispensed paroxetine 20mg daily for him. As far as you know, this is all he is taking.

He is admitted to his local hospital with some symptoms including restlessness, sweating and a lot of twitching. Doctors there reduce his morphine dosage as they think this may be responsible for the twitching and other symptoms. However, John's condition worsens and he is transferred to another ward, because his worsening symptoms are interpreted as indicating that he is now dying.

The ward staff felt that, although some of John's symptoms could indicate that he is in the last stages of his illness, something isn't quite right. Equally, it is difficult to understand why his twitching and other symptoms could be due to the morphine as his dose hadn't been changed for some time and he had been tolerating it well.

An observant doctor thought his symptoms were consistent with serotonin syndrome – a rare but potentially fatal condition which can occur when two drugs known to increase serotonin levels are given concomitantly.

However, all the information from his wife and his GP suggested that he was taking only morphine and paroxetine as indicated above, plus chemotherapy drugs at the hospital oncology department.

What is serotonin syndrome?
Serotonin syndrome is a rare condition that is becoming increasingly well recognised in patients receiving more than one drug affecting the levels of the neurotransmitter serotonin. Using an irreversible monoamine oxidase inhibitor (MAOI) with a serotonergic agent is the most toxic reported combination, but any drug or combination that increases serotonin levels can, in theory, cause the syndrome.

It is characterised by a variety of autonomic, neuromotor and cognitive-behavioural symptoms including agitation, confusion, diaphoresis (sweating), hallucinations, exaggerated reflexes (hyperreflexia), myoclonus (twitching), shivering, tachycardia and tremor. Diagnosis is made when at least three of these symptoms are present with no other obvious cause.

It can occur when one serotonergic drug is switched to another without an appropriate 'wash out' period, and can also occur when two or more drugs affecting serotonin levels are given at the same time.

The syndrome is relatively mild if recognised early and resolves when the offending medicines are stopped. However, it can be severe and sometimes fatal. There is no treatment.

The most severe reactions are usually associated with SSRIs plus MAOIs, both with non-selective MAOIs such as phenelzine and selective MAOIs such as moclobemide and selegiline. A large number of

drugs have been implicated, including pethidine (watchers of the American drama programme *ER* might have noticed a recent ease involving a pethidine [meperidine] injection given to a patient admitted from a nursing home who was being treated with an MAOI).

There are reports of amphetamines and ecstasy (MDMA), taken in conjunction with MAOIs or SSRIs, causing the syndrome. Serotonin syndrome has occurred with MAOIs and SSRIs when given in combination with dextromethorphan, found in over the counter cough and cold remedies.

Other culprits include some of the atypical antipsychotic drugs such as risperidone and olanzapine used with SSRIs.

Lithium has been implicated, as have serotonin receptor agonists such as sumatriptan and other "triptans" used for migraine.

Sibutramine, for weight reduction, is also serotonergic so patients wanting to lose weight with this treatment may be safer discontinuing SSRIs (or MAOIs) and allowing a suitable 'wash out' period first.

What about John?

In John's case, it was soon found that at his last oncology appointment at the specialist hospital three weeks earlier he had been prescribed fluoxetine and had been taking this in addition to his paroxetine. He had not questioned this as he had confused fluoxetine with the drug fluconazole, which he had frequently been prescribed for oral candidiasis caused by his chemotherapy. Because it was dispensed by the hospital's pharmacy, no one at the hospital realised he was also taking paroxetine.

It is not known whether the hospital staff had intended to prescribe fluoxetine (and if so, why they hadn't asked John if he was taking any other antidepressant) or, instead, fluconazole. Although the specialist hospital would update the GP on drugs prescribed, this hadn't happened at the time of John's crisis.

Fortunately, the quick recognition of the syndrome by the observant doctor meant that John recovered from the crisis. He was restarted on a low dose of an SSRI and lived a few more months before dying of his cancer.

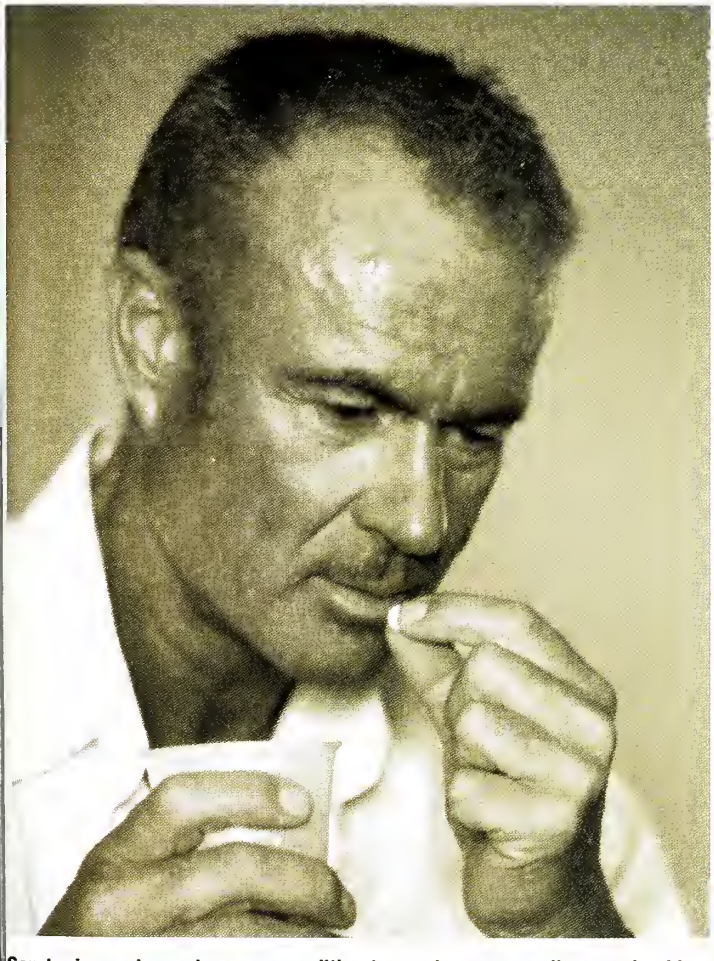
Could John's community pharmacist have helped prevent the crisis? Possibly not, as the second SSRI was prescribed from the specialist hospital and led to the crisis before information was communicated to the GP. However, in general, where several agencies are prescribing for a patient it might be useful for all information about medicines prescribed for an individual patient to be communicated to the patient's community pharmacy.

It is probably true to say that, for many (possibly most) patients receiving multi-agency care, none of the different agencies involved will have a complete list of all the drugs prescribed for that patient – a disturbing thought.

When patients first start taking antidepressants, there is a lot to discuss in checking that they understand the use, immediate potential side effects, and delayed onset of action.

It is all too easy for pharmacists to overlook reminding the patient to tell all doctors involved in their care about all the drugs they have been prescribed, but it is important to try to make time to reinforce this message. Specialist doctors may consider only their own speciality, and patients may not otherwise consider it relevant to list drugs prescribed in primary care to their specialists, particularly when appointment times are tight and there are seemingly more important priorities to discuss.

Mary Allen, FRPharmS, is a part-time community pharmacist and hospice pharmacist in Herts.



Serotonin syndrome is a rare condition becoming more well recognised in patients receiving more than one drug affecting serotonin levels

Useful information

Information on swapping and stopping antidepressants is available in *The Maudsley Prescribing Guidelines, 7th edition 2003, Taylor D et al*, published by Martin Dunitz, *www.dunitz.co.uk* (sometimes available via pharmaceutical company representatives). *See also C&D Pharmacy Update July 10.*

Actionplan

1. Record in your practice workbook up to four patients who have or have had cancer. List their current drug regimens and, where possible, the site of their cancer.
2. Using this as a base, list the common adverse effects you would expect to see in such patients.
3. Do any of these patients report these side effects? If so, what advice or help can you give?
4. Revise the doses of SSRIs, paying particular attention to those for the elderly and patients who are less homeostable than average. Revise your knowledge of diabetes insipidus and the way the kidneys maintain electrolyte balance.
5. Read the 'Prescribing for the elderly' section in the *British National Formulary*. In your practice workbook note the guidelines and then search reference sources to elaborate the points made.

Distance learning for pharmacists

Pharmacists using **Pharmacy Update** for continuing education are reminded of the need to test. With the support of Genus Pharmaceuticals, *C&D*'s readers can self-test their progress by using the multiple choice question (MCQ) paper to be inserted in the August 7 issue, which will cover this week's CPP-accredited modules together with those in the July 10 and 17 issues. These will cover:

- **Coming off SSRIs (1308)**
- **Ankylosing spondylitis (1309)**
- **SSRIs in cancer (1310).**

A telephone marking service offers independent verification of results – details on the monthly MCQ papers. People wanting to register for Pharmacy Update can contact Mary Prebble on 01732 377269.

C&D in association with GENUS PHARMACEUTICALS

Suicide risk similar for SSRIs and tricyclics

Suicide risk in patients is similar in those using SSRIs or tricyclic antidepressants, claim researchers in the US.

Patients using fluoxetine, paroxetine or amitriptyline did experience an increase in suicidal behaviour in the first month – and especially in the first nine days – but there was little difference between the drugs, say the researchers. An elevated risk for paroxetine users was seen, which the researchers said could be due to confounding of data due to the severity of depression with these patients.

Approximately 121,300 patients taking fluoxetine, paroxetine and amitriptyline were compared to nearly 46,600 patients taking dothiepin and their patient records were searched for suicidal behaviour while on the antidepressant medication. The researchers also looked at the data for adolescents aged 10 to 19 years old. "Based on limited information, we also conclude that there is no substantial difference in the effect of the four drugs on people aged 10 to 19 years," the authors wrote but warned that data for this patient group was limited.

The authors claimed the study "provides evidence that the risk of suicidal behaviour is not substantially different among patients starting treatment with amitriptyline, fluoxetine or paroxetine than among patients starting treatment with dothiepin".

For more information:

JAMA 2004; 292: 338-343

Levodopa and pramipexole equal options for PD

Pramipexole and carbidopa/levodopa treatments are reasonable options as initial therapies for Parkinson's disease, but differences lie in their efficacy and adverse effects, say researchers.

Patients randomised to pramipexole were less likely to develop dyskinesias (about one quarter compared to more than 50 per cent of levodopa patients) and 'wearing off' (47 per cent compared to almost 63 per cent on levodopa). However, patients on levodopa fared better with fewer incidences of 'freezing', somnolence and oedema, and better symptom control, claim the researchers.

During the four years of the trial, both drug regimens resulted in similar quality of life for the patients. This finding led the authors to conclude that both treatments "appear to be reasonable options as initial dopaminergic therapy in Parkinson's disease", despite their differences in efficacy and adverse effects.

The US study followed 151 patients on pramipexole therapy (initially 0.25mg, 0.5mg or 1mg tid) and 150 patients on carbidopa/levodopa therapy (25/100mg tid). Dosage was increased to 1.5mg pramipexole or 75/300mg carbidopa/levodopa over 10 weeks; patients with severe symptoms could increase their dose further. The subjects were followed for four years.

For more information:

Arch Neurol 2004; 61:1044-53

Scriptlines

Vaniqa

Shire Pharmaceuticals is launching Vaniqa 11.5 per cent w/w cream (eflornithine monohydrate chloride 115mg) for the treatment of facial hirsutism in women.

Eflornithine is an antiprotozoal that acts as an irreversible inhibitor of ornithine decarboxylase. Patients should apply a thin layer of the cream to clean and dry affected areas on the face or under the chin twice daily, with at least an eight-hour interval between treatments. The cream should be applied so that no residual product can be seen on the skin and the patient should wash their hands after use. For best results, the treated area should not be cleansed for four hours after application. Cosmetics and sunscreens can be used over the treated areas, but only after waiting five minutes after application.

Patients may see an improvement in their condition within eight weeks of starting treatment, but should discontinue use if no improvement is seen after four months of therapy. Irritation may occur, and patients should temporarily reduce the applications to once daily. If irritation continues, treatment should be stopped and the patient should consult their GP.

Common side effects include mild acne, burning, stinging, tingling, rash and erythema.

Vaniqa is not suitable for women who are pregnant or planning pregnancy or are breast-feeding.

For more information:

See Price List

Shire Pharmaceuticals

Tel: 01256 894000

Budenofalk SPC change

Budenofalk (budesonide) is now licensed for the symptomatic relief of chronic diarrhoea due to collagenous colitis.

The dosage remains the same at one capsule three times a day taken 30 minutes before meals with plenty of water.

For more information:

http://emc.medicines.org.uk

Provalis

Tel: 01244 288888

Pariet SPC change

Pariet (rabeprazole) is now licensed to treat Zollinger-Ellison syndrome, a severe form of stomach and duodenal ulceration.

The recommended starting dose for adults is 60mg once daily. The dose can be titrated up to 120mg per day, which may be given in divided doses. Single daily doses of 100mg may be given; treatment should continue for as long as clinically indicated. Pariet tablets should be swallowed whole, not crushed or chewed.

For more information:

http://emc.medicines.org.uk

Eisai

Tel: 020 8600 1400

Suprax gets bigger

Aventis has relaunched Suprax powder for paediatric oral suspension in two new larger sizes 50ml and 100ml (both contain 100mg/5ml cefixime). The product remains the same.

For more information:

See Price List

Aventis

Tel: 01732 584000

UniChem launches own-brand omeprazole

UniChem is introducing own-brand omeprazole tablets which are among the first own-brand omeprazole products to be available OTC.

UniChem Heartburn Relief 10mg Tablets are indicated for the relief of reflux-like symptoms in patients aged 18 or over and may be particularly useful for those whose symptoms are intermittent, predictable or relapsing.

Initially the dose is 20mg once daily and this may be reduced to 10mg daily, returning to 20mg if symptoms return. The majority of people should receive maximum benefit within three to four days.

Training literature is available for pharmacists and assistants.

As an introductory offer, the pack will be available for £2.01 plus VAT (trade price) until the end of August when it will increase to £2.39 plus VAT.

Price: £6.99

Pack size: 14 tablets
Pip code: 303-6084
UniChem Ltd
Tel: 020 8391 2323

Fresh look for Dioralyte

Aventis Pharma is introducing a bright new look for Dioralyte and Dioralyte Relief.

Dioralyte Relief is now GSL and the new packaging reflects this status. The rehydration treatment has anti-diarrhoeal properties and is available in raspberry and blackcurrant flavours

The new packs will be available from August 1.

Price: Dioralyte £3.39, Dioralyte Relief £3.79

Pack size: six sachets
Chemist Brokers Healthcare Division
Tel: 023 9222 2500

Mossie net in an instant

A mosquito net that needs no separate hanging device or external support is being launched into pharmacies.

Mosinet is a lightweight net made from polyester and is normally supplied pre-treated with permethrin. It can be supplied untreated if requested.

The net is designed to be easy to erect and is available to fit single or double beds. It folds almost flat, making it suitable for travelling and comes in its own carry bag.

Price: single bed £34.50, double bed £77.99

Instant Mosquito Net Company Ltd
Tel: 01892 852961

Name change for Galsud Linctus

Thornton & Ross is relaunching Galpseud Linctus in a new OTC pack with a different name – Galsud Linctus.

The move follows the recent relaunch of Galpseud Tablets as Galsud Tablets.

The name change is designed to make the product easier to read and pronounce.

Galsud Linctus is an oral, sugar-free nasal decongestant containing pseudoephedrine hydrochloride. It is formulated to relieve nasal, sinus and upper respiratory congestion without causing drowsiness. The product is suitable for adults and children over the age of two years.

Price: £2.79

Pack size: 100ml
Pip code: 033-1645
Thornton & Ross Ltd
Tel: 01484 842217

Threadworm action month

Thornton & Ross is supporting a threadworm action month from September 6 to coincide with children returning to school.

Parents will be urged to check for symptoms and see a pharmacist if they are concerned.

For more information:

Thornton & Ross
Tel: 01484 848200

Frontshop

Smoothing the way

Collection 2000 is improving its Natural Matt Foundation to provide a longer lasting matt finish for a smooth complexion.

The creamy foundation now contains grape extract to improve the skin's elasticity and help fight free radicals. The fragrance-free formulation gives oil-free coverage and contains vitamin E and UVA/UVB sunscreens.

The product is available in six shades – Ivory, Blonde, Beige, Almond, Amber and Bronze – and will be available in October.

Price: £2.49

Pack size: 40ml
Collection 2000 Ltd
Tel: 01695 727317

Coolhogs go colourful

Kent Brushes is expanding the range of colours for its Coolhogs hair brushes.

The brushes are now available in lilac, green, blue, pink and yellow. Suitable for all hair types, the brushes feature hog quills with protective ball ends and can be used to detangle wet hair.

Price: £5.25

GB Kent & Sons Ltd
Tel: 01442 232623

A close shave out of the blue

A shaving kit that makes a practical male gift is being launched into pharmacies.

The Flavashave set contains shave gel, a pure bristle shaving brush and shave enhancer.

The gel, which has an invigorating spearmint fragrance, is massaged into the beard area with the traditional shaving brush.

The shave enhancer is designed to reduce the risk of shaving rashes by removing the calcium and magnesium ions from water – softening the water and giving maximum razor glide. A small amount of the blue liquid is added to the shaving water.

Price: £9.99

Pack size: shave gel 100ml, shave enhancer 250ml
A.C.T. Products (UK) Ltd
Tel: 01923 442230

Alberto gets all fruity

Alberto-Culver will launch three new shampoos and conditioners into its Alberto Balsam range in October.

Strawberries and Cream shampoo and conditioner for coloured hair are fragranced with strawberries and the sweet smell of vanilla cream.

Creamy Fresh Peaches shampoo and conditioner are formulated to leave frizzy and unmanageable hair silky smooth and shiny.

Both products contain soymilk proteins and fruit extracts to help protect and nourish the hair plus pro-vitamin B5 to help strengthen the hair.

Sun Kissed Blonde Herbal shampoo and conditioner is formulated to give summer lights to blonde and highlighted hair. Both products contain extracts of chamomile and lemon plus pro-vitamin B5.

Price: £1.59

Pack size: 400ml
Alberto-Culver Co (UK) Ltd
Tel: 01256 705000

Gucci scent to be Envied

Cosmopolitan Cosmetics is launching a new Gucci fragrance for women.

Gucci Envy Me will initially be exclusive to Harrods from August 23 and will be available to pharmacies on September 24.

Described as a floral musky fruity scent, it is presented in a pink-printed crystal flacon.

The range includes three sizes of eau de toilette spray (30ml, 50ml and 100ml), body lotion and bath and shower gel.

Price: from £23.00 for 200ml bath and shower gel to £55.00 for 100ml eau de toilette.

Cosmopolitan Cosmetics UK Ltd
Tel: 020 7297 5000

Radian B backs run

Radian B is co-sponsoring the Feelfine British 10K Run around central London on August 1.

The sponsorship offers runners access to a massage area where they will be able to get pre-race warm up treatments as well as post-race recovery massage.

A proportion of the proceeds from the massage will be donated to the Muscular Dystrophy Campaign and a free Radian B sports bag will be given to each customer.

For more information:

Ransom Consumer Healthcare
Tel: 01462 437615

TV next week

Anadin: All areas
Bisodol: Sat
Bodyform: C4, five, GMTV, Sat
Califig: C4, Sat
Gavilast: All areas except TT
Gaviscon: All areas except TT
Germoloids HC Spray: C4
Imodium Plus Caplets: All areas
Lamisil: All areas
Listerine: All areas except U, GMTV
Nicorette: All areas except U, GMTV
Odoreaters: All areas
Pro Plus: GTV, B, G, Y, LWT, CAR, TT, C4, five, Sat
Scholl Flight Socks: GMTV
Simple Oil Control: five
Traveleeze soft & chewy pastilles: GMTV
Veet Bladeless Razor: All areas
Veet Ready to Use Strips: All areas
Vagisil: All areas
PharmaSite for next week: Savlon dry antiseptic, Waterproof plasters, Antiseptic wound wash – window, **Nurofen Plus** – in-store, **Refresh eye drops** – dispensary

A-Anglia, B-Border, C-Central, C4-Channel 4, Five-Channel 5, CAR-Carlton, CTV-Channel Islands, G-Granada, GMTV-Breakfast Television, HTV-Grampian, HTV-Wales & West, LWT-London Weekend, M-Meridian, Sat-Satellite, STV-Scotland (central), TT-Tyne Tees, U-Ulster, W-Westcountry, Y-Yorkshire

Frontshop

Rapid response unit is a lifesaver

Next of Kin is launching an emergency response unit suitable for people with diabetes, a medical condition or an allergy.

Diabetes Lifeline & Medical Response can provide vital medical information in seconds which could be lifesaving in an emergency.

The user will also be covered anywhere in the world by The Next of Kin service so family members can be contacted within minutes. The company is recognised by The Association of Chief Police Officers.

A carton containing 18 units comes with a free counter display stand. Pharmacies are being offered an introductory trade price of £8.15 plus VAT for each unit.

Price: £19.95

Next of Kin Ltd
Tel: 0845 890 3047

Continence advice online

National charity the Continence Foundation has launched a free online product directory listing all continence products available in the UK.

The directory provides a discreet way for those with bladder and bowel weaknesses to find out about specialist continence pads and pants etc.

For more information:

www.continence-foundation.org.uk/directory

Kool 'n' Soothe that racket

Kobayashi is supporting Kool 'n' Soothe Migraine with advertising on GMTV and satellite TV during August and September.

The TV commercial shows a mother having to endure the pain of her daughter practising the violin to illustrate how everyday events can lead to a severe headache or migraine.

The advertising will be reinforced in pharmacy with price promotions and sampling targeted at pharmacists and assistants.

The campaign is part of a £2 million investment which will include national TV advertising for Kool 'n' Soothe products and Cura-Heat until May 2005.

For more information:

Maverick Sales & Marketing Ltd
Tel: 01628 478555

New distributor

Acnisal, Meted, Occlusal and Pentrax will be distributed by Alliance Pharmaceuticals from August 2. This follows the acquisition of DermaPharm by Alliance earlier this year.

For more information:

Alliance Pharmaceuticals Ltd
Tel: 01249 466974

Legs on the web

Boehringer Ingelheim is launching a new website for its Antistax range. The site is designed to educate and offer practical solutions to consumers who experience aching, tired and heavy legs. It includes information on the Antistax range, exercises and dietary recommendations from health experts.

For more information:

www.antistax.co.uk

With the summer holiday season here, we asked you about travel health via the Intr@PharmQ online survey

Q1. Does your pharmacy have a section dedicated to travel health?

	No of Responses	% of base
Yes – year round	33	30
Yes – seasonal for summer holidays	33	30
No	44	40

Q2. In which aspects of travel health would you appreciate more training (select up to five)?

Q3. Which of the categories mentioned in Q2 do customers most want to know about? (Up to five options could be selected)

	Q2 % of base	Q3 % of base
Anti-malarials	43	84
Water borne infections (eg cholera, typhus, hepatitis A, polio)	37	4
Human borne infections (eg TB, diphtheria)	35	4
Vaccinations	33	43
DVT	33	30
Other insect-borne diseases (eg dengue, Lyme disease)	32	2
Climate and environment (sun stroke/frost bite/ altitude sickness)	32	11
Overseas healthcare provision	30	4
Specific patient groups (eg pregnant/nursing mothers, infants, or the elderly)	27	13
Travel health in general	23	17
General first aid	22	16
Motion sickness	22	41
Bites and stings	20	59
Dealing with diarrhoea	19	59
Diet/nutrition/hydration	13	6
Sexually transmitted diseases	8	2
HIV	4	3

Q4. Would you be happy to run a travel vaccination service in your pharmacy?

	% of base
Yes – if I had sufficient training	60
Yes – if a health professional specialising in travel were to vaccinate the patients	25
No	15

Q5. Where are you going for your summer holiday this year?

UK	19
Mediterranean	14
Far East	10
Africa	6
Northern Europe	5
USA/North America	5
Central/Eastern Europe	5
Caribbean	3
Somewhere else /other	5
Not having a summer holiday	26

Intr@PharmQ is an online survey of community pharmacists conducted by IMS. The online survey ran from June 12 to July 7 and 110 community pharmacist responded

PAGB

In its 85th anniversary year PAGB continues its series of articles reviewing key topical issues around self-care. This article, the third, reviews the main regulatory changes of the last few years that are influencing the advance of self-care

Many of the regulatory barriers to the growth of self-care have come down so the OTC industry and health professionals should seize the opportunity and move self-medication forward, says Mike Owen, PAGB communications and commercial affairs director

The way forward

Think back to the late 1990s. Self-care was not a noticeable feature of healthcare policy. There was little governmental or regulatory encouragement for wider OTC medicine innovation, with strong curbs on advertising and a difficult switch application process to navigate. Most of the less contentious switches had already been undertaken, including, most recently, hay fever, dyspepsia and nicotine replacement therapy, and the pool of ingredients with clear OTC potential was starting to dry up.

Move on a few years, though, and the OTC landscape – particularly the regulatory environment – started to look quite different. What regulatory changes have there been and why should pharmacists respond positively to them? Enter *The NHS Plan* in July 2000.[1] For the first time, this established self-care as a key element in the future design of healthcare in the UK, and, in particular, recognised the greater role of self-medication.

Easier switch process

The 2000 *Plan* led the Medicines Control Agency (MCA) to form a 'reclassification advisory group' of health sector stakeholders – including representatives from industry (PAGB, ABPI), professional bodies (RPSGB and RCGP) and patient representatives – to consider fresh ways of stimulating greater accessibility to medicines by encouraging more POM to P switches. The work of the group led to three significant developments:

1. A streamlining and simplification of the switch application process, with an end to set timetables for switches.
2. A shift in regulatory policy such that the legal classification for a product became part of its marketing authorisation, avoiding the need for secondary legislation.
3. A report setting out an 'aspirational' list of suggested therapeutic categories and indications that might be suitable in the future for P status products, with a focus on more chronic conditions (*see panel A opposite*).

Alongside these developments a working group headed by PAGB looked into the information and pharmacy training requirements of potential future switches. This produced a report that stressed how companies with POM to P candidates need to consult closely with health professional groups ahead of a switch and particularly provide extensive training (including support materials for treatment protocols and self-help advice to give to patients).

Collectively, these developments produced a trumpet call to the OTC industry to gear up their switch development pipeline. In fact, when the Government implemented the simpler switch process, it declared that it hoped to see 50 new switches by 2007. This was a doubling of the pace seen over the previous 10 years. The next article in this series will look at the issues around this aspiration.

Advertising and branding

Advertising is crucial to an over the counter medicine. The OTC industry spends over £100 million in the UK on advertising and promotion to make consumers aware of their products and to help educate consumers about the range of conditions that can be treated with OTC medicines. Without advertising it is not viable to launch a new OTC product and far fewer consumers would be led to visit pharmacies to look for OTC treatments.

Up to very recently OTC medicines could only be advertised for a traditional range of well-established, self-limiting conditions. This month, though, the MHRA lifted restrictions on 13 significant therapeutic areas (*see panel B opposite*) including cardiovascular diseases and more serious chronic conditions. This opens up the potential of seeing new OTC products to suit long-term conditions, as manufacturers see they can promote what they have to offer and are stimulated to develop a wider OTC portfolio.

This measure was seen by the Government as critical to spurring the development and availability of more over the counter medicines and helping to empower individuals in looking after themselves more. The health minister, Lord Warner, declared: "Removing the restrictions ... has the potential to bring real public health benefits by giving more power and information direct to patients".[2]

But making it easier to advertise must, of course, be balanced by the need to ensure that all advertising is responsible so that patient safety is protected. All OTC advertising – aimed at either consumers or health professionals – is carefully controlled by a combination of legal regulation and self-regulatory codes, including PAGB's code for consumer advertising and its code for advertising aimed at health professionals, bot

of which have recently been updated and are viewable on PAGB's website.[3]

To help ensure responsible advertising for the wider range of therapeutic areas, PAGB, following consultation with the industry, healthcare professionals and patient groups, has developed a set of *Best Practice Guidelines* for the industry. The guidelines are supplementary to the statutory and self-regulatory frameworks and include specific requirements for individual drugs, conditions and therapeutic areas, so as to ensure safe use of the product.

One of the first products to benefit from the adjusted advertising restrictions is likely to be simvastatin 10mg, which the Committee on Safety of Medicines (CSM) has advised can be safely sold through pharmacies to reduce the risk of a first major coronary event in people likely to be at moderate risk of coronary heart disease (CHD).

Closely related to advertising is the issue of branding for medicines. OTC manufacturers take brands extremely seriously because most consumers don't actually think in terms of ingredients – like pharmacists do – when they buy over the counter medicines. Brands help consumers to build up trust and confidence in products, simplify choice and selection when shopping, stimulate innovation in the market, and give a platform to manufacturers to differentiate their advertising and help make new launches more viable.

Early this year the MHRA, in co-operation with industry, issued a guideline on the product naming of OTC medicines.[4] This contained a useful checklist for reference by manufacturers when planning product line extensions and new products. It is a welcome step on the road to a more widespread, pragmatic understanding of the appropriate use of branding with consumer medicines.

2001 Review

The 2001 review of EU-based pharmaceutical legislation is the source of other, significant measures that affect the UK OTC sector.

One of the most welcome measures has been the granting of a one-year data exclusivity/protection for POM to P switches, which will be of some help in encouraging new switches to be developed.[5] The review also established the same data protection for new indications for established substances (for an established P product as much as for a switch). The precise interpretation of the new provisions has still to be clarified but this is expected soon. The measure will come into UK law at the latest by next autumn.

The area of product labelling is also dealt with by the review. Changes affecting OTC manufacturers include the requirement to do user readability testing of product leaflets, the need to meet the needs of visually-impaired medicine users and the need for product packs to contain details of each active ingredient if the product has up to three.

Leaflets are the subject of interest of several review groups across Europe, including a dedicated working group under the auspices of the CSM. There is clearly a widespread desire to see how consumers can be better informed and empowered more about the medicines they take.

Panel A

List of therapeutic categories suggested in 2001 as possibilities for future P status (following work of the 'Reclassification Alliance')

1. Gastro-oesophageal reflux disease
2. Stable angina
3. Hypertension
4. Stroke and myocardial infarction
5. Chronic obstructive pulmonary disease/stable asthma
6. Influenza
7. Obesity
8. Migraine
9. Anxiety
10. Malaria prophylaxis
11. Post-menopausal osteoporosis
12. Long-term contraception
13. Menopause
14. Erectile dysfunction
15. Urinary incontinence
16. Rheumatic and arthritic pain
17. Eye infections
18. Acne
19. Psoriasis

Panel B

List of therapeutic areas for which advertising restrictions were lifted July 2004

1. Bone diseases
2. Cardiovascular diseases
3. Diseases of the liver, biliary system and pancreas
4. Endocrine diseases
5. Genetic disorders
6. Joint, rheumatic and collagen diseases
7. Psychiatric diseases
8. Serious disorders of the eye and ear
9. Serious gastrointestinal diseases
10. Serious neurological and muscular diseases
11. Serious renal disease
12. Serious respiratory disease
13. Serious skin disorders

Food and herbal Directives

A new regulation affecting the food supplements side of the self-care market is in the form of a dedicated EU Directive.[6] This establishes a definition of the term 'food supplement', gives a list of the vitamins and minerals that may be used in food supplements, gives a list of permitted sources of vitamins and minerals and introduces mandatory labelling requirements for food supplements beyond those that apply already to most foodstuffs. The Directive will also eventually define maximum intake levels for vitamins and minerals, but this will take a few years yet. The Directive was adopted into UK law last year but we still await the outcome of a court case which questions the legitimacy of the Directive.

Related to this Directive is the EU Regulation on Health and Nutrition Claims.[7] This seeks to establish a list of acceptable health and nutrition claims (eg 'helps to reduce cholesterol') that can be attached to food products, including food supplements. The regulation did not go through the last European Parliament and will be presented again later this year. Implementation into UK law will take a couple of years.

The Traditional Herbal Medicinal Products Directive is also worth noting.[8] This introduces registration for herbal products that have been traditionally used as medicines over a long period. It will come into effect in the autumn of 2005, but manufacturers have until 2011 to get their established products registered or withdraw them from the market.

People as well as medicines

It is important to remember, of course, that the changing regulatory environment is not only about controls over medicines. The Government has been particularly concerned over the last few years – partly prompted by some high-profile misconduct cases amongst certain health professionals and stories of poor standards at hospitals – to ensure robust and clear regulation over health professionals themselves and over the quality and outcomes of the work and procedures they deal with. This is affecting not just 'established' professionals like pharmacists, GPs and dentists but also support staff such as dispensing and counter assistants, as well as wider groups such as herbalists and acupuncturists.

Safety still paramount

Despite the encouragement of more switches from some of the above regulatory changes, safety remains the top concern in the licensing and regulatory processes used with medicines. The MHRA's reclassification criteria stipulate that "before a medicine can be switched from POM to P, ministers must be satisfied that it would be safe to allow it to be supplied without a prescription".

A major control in the supply of any medicine, of course, is the pharmacist himself for whom the RPSGB's Code of Ethics and Standards is intended to ensure relevant and appropriate questions and advice are shared with patients at point of delivery.

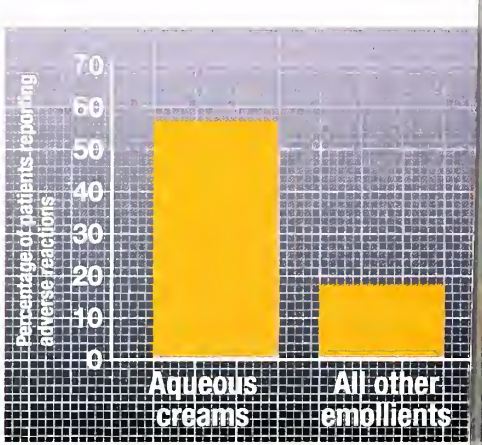
Adverse Drug Reaction reporting is another important safety measure and the recent piloting by NHS Direct Online of direct reporting of adverse reactions by consumers is noteworthy. Similarly, the wider, proactive role and interest of the National Patient Safety Agency (NPSA) in receiving reports from health professionals on safety incidents and tracking wider safety trends is significant.[9]

The overall message is clear. The regulatory environment has been changing to make self-care easier. Crucially, this has been mostly in terms of helping to improve communications and accessibility regarding OTC medicines and improving regulatory procedures rather than lowering or compromising absolute standards of areas like safety. Pharmacists should, therefore, view the regulatory changes positively and grasp the wider professional opportunities offered by the growth of self-care.

References available on request.

skin wars

Figure1. Adverse reactions to emollients



The proportion of episodes of exposure to emollients were associated with immediate cutaneous reactions. the 100 children audited, 71 had used aqueous crear and of these 40 (56.3 per cent) had developed an immediate cutaneous reaction. There were 622 episo of exposure to all other emollients resulting in 111 immediate cutaneous reactions (17.8 per cent)

Dermatologist Michael J Cork explains why he and his colleagues* no longer recommend aqueous cream as a leave-on emollient for children with eczema

In 2003, my colleagues and I reported an audit of adverse drug reactions to emollients in children with atopic eczema.[1] We showed that 56 per cent of episodes of exposure to aqueous cream in 100 children with atopic eczema were associated with immediate cutaneous reactions. In contrast all other emollients, including proprietary creams and emulsifying ointment, were not associated with a high frequency of such reactions (17 per cent of episodes of exposure).

The reactions to aqueous cream were so common that we recommended it should be used only as a soap substitute and not as a 'leave on' emollient. When used as a soap substitute it is only in contact with the skin for a short time.

Finding the most suitable emollient may be a matter of trial and error.[3] In theory, greasier oil-based products are more effective but these are rarely tolerated because of their poor cosmetic acceptability and so are not used by people with mild or moderate atopic eczema. The best emollient is the one the patient prefers, because he or she will use it more regularly.

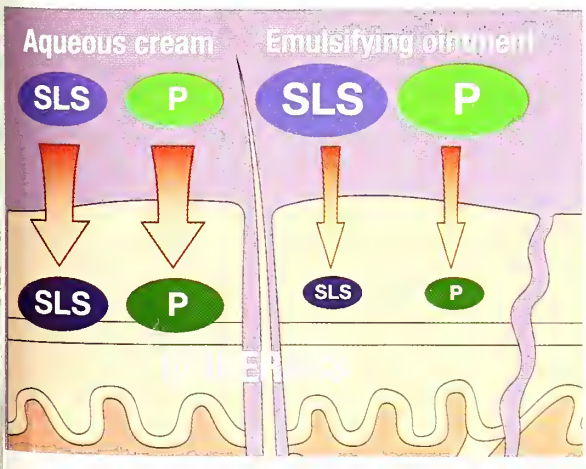
To enhance compliance in children we have developed a child-orientated approach to teach them about eczema and its treatment - 'Skin wars'.[4] Children pick their favourite emollient from a tray containing all the emollients in the *BNF*, which empowers them to use their chosen emollients.[2] We ask the children and parents to report any previous adverse reactions to emollients they have used, such as burning, stinging and redness of the skin. We noticed that adverse reactions following the use of aqueous cream in children were more frequent than to any other emollient cream or ointment. This led to the formal audit, mentioned above, of children attending our paediatric dermatology clinic. The adverse reactions occur within 20 minutes of applying the emollient and can be reproduced by applying test patches of an emollient on to the child's arm.

The study raised many questions, the most obvious being – why were there more reactions to 'leave on' aqueous cream but not to emulsifying ointment, when aqueous cream BP is composed of emulsifying ointment 30 per cent and 70 per cent purified water? Both preparations contain the detergent sodium lauryl sulphate (SLS) and the preservatives chlorocresol or phenoxyethanol, which are likely to cause irritant reactions. The concentration of these ingredients is much higher in emulsifying ointment than aqueous cream, but the reason aqueous cream causes more reactions is because of the different partitioning of ingredients from creams and ointments into the skin.

This phenomenon of differential partitioning was eloquently explained by Hadgraft *et al.*[5] They suggested that the caustic properties of phenol on the skin could be reduced substantially by putting the phenol into oil. Phenol in water caused erythema of the skin while the same concentration of phenol in oil did not. Similar observations have been made for methylnicotinate.[5,6] In an ointment containing high concentrations of oils, ingredients such as phenol and methyl-nicotinate are trapped in the oil and little partitions into the skin. By contrast, in a cream formulation the ingredients readily partition from the aqueous phase into the skin. This differential partitioning explains why irritant cutaneous reactions are more common with aqueous cream (used as a 'leave on' emollient) than emulsifying ointment (*see figure 2*).

Once a detergent such as SLS has penetrated into the upper layers of the stratum corneum it has several negative effects on the skin barrier including damage to the lipid lamellae.[7] SLS also raises the pH of the skin, which can enhance the activity of endogenous proteases that can break down the skin barrier.[8] The reason aqueous cream does not usually adversely affect the skin barrier when used as a soap substitute is that the contact time is only a couple of minutes. The problem with aqueous cream is not the formulation itself but using a product designed as a 'wash off' soap substitute as a 'leave on' emollient.

Figure 2. Partitioning of detergents and preservatives from cream and ointment formulations



There is a higher concentration of the detergent SLS and the preservative chlorocresol in emulsifying ointment than aqueous cream. But there is differential partitioning from ointments and creams so a larger quantity of these ingredients reaches the skin from aqueous cream when these products are left in contact with the skin

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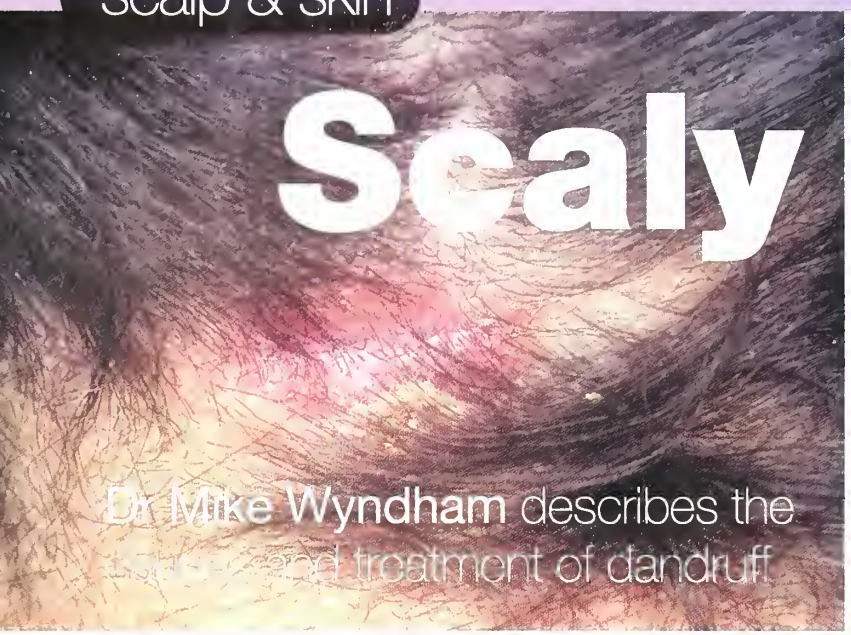
**John Timmins is at Sheffield Children's NHS Trust Pharmacy Department; Catherine Holden, Julie Carr and Victoria Berry are at Sheffield Children's Hospital, while Darren Robinson, Rachid Tazi-Ahnini and Simon Ward are from the Division of Genomic Medicine, Royal Hallamshire Hospital, Sheffield.*

Scaly scalps



Dr Mike Wyndham describes the [illegible] and treatment of dandruff

Dandruff represents a mild form of seborrheic dermatitis. It is a condition that appears to be more common in men and manifests usually in adulthood. Research suggests that sebum-producing cells respond to stimulation from male hormones, perhaps accounting for the male preponderance.

Pityrosporum ovale is a yeast that has been implicated in the development of dandruff.[1] However, it may be found on the skin of most individuals, some of whom do not suffer from dandruff. Nevertheless, treatment with antifungal shampoos will definitely improve the condition.

Seborrheic dermatitis is more prevalent in certain conditions such as Parkinson's disease. Indeed, drugs that induce Parkinson's disease may be associated with the dermatitis.[3] HIV disease may manifest with an extensive seborrheic dermatitis, the cause of which is unknown but postulated to relate to immunodeficiency. The condition is more common in winter, perhaps explained by the fact that growth of *P ovale* is inhibited by ultraviolet light.

The clinical manifestations of dandruff are known to us all. A white scale develops on the scalp and may be associated with irritation. When it falls on to the shoulders, the scale can be an embarrassment. It is a good idea for sufferers to wear light coloured clothing when the condition is bad. The social manifestations of skin disease should never be underestimated.

Where the condition is more severe, a greasy scale may be present on the scalp and may extend to the eyebrows, naso-labial folds, behind the ears and beard area. Blepharitis may be present as well. The rash may extend onto the chest with either the formation of papules/patches associated with scale. While the scalp may itch, areas such as the naso-labial folds may feel sore.

When offering advice to patients, it is important for pharmacists to consider other possible conditions that may cause scaling of the scalp, so as to avoid incorrect management. Fungal infection of the scalp in children may cause an area of alopecia with red scaly skin. The age helps in deciding here, remembering that dandruff occurs in the adult patient.

In psoriasis, areas of the scalp may become covered in a thick scale that may be raised to form thick plaques. The scale may also 'grow' along the hair shaft, so it may be useful to enquire if there are any dermatological manifestations

elsewhere. Common areas for psoriasis include extensor surfaces of the elbows and knees, the umbilicus and natal cleft. Dandruff produces a fine powdery scale rather than a thick one and does not manifest in the areas mentioned for psoriasis.

The nits of head lice may also be confused with dandruff. Personally, I would recommend what I call the 'flick test': in dandruff, the scale is easily dislodged from the hair shaft whereas the nit case is tightly attached.

Advice

So what advice should be offered to the dandruff sufferer? Firstly, patients should regularly brush their hair to remove scale and debris. Regular washing will remove any excess sebum. It may be a good idea to avoid mousse, hair spray and instruments such as heated hair straighteners.

Cases that do not respond to non-prescription treatments, correctly used, should be referred to a GP.

Treatments

Selenium sulphide. Selenium sulphide 2.5 per cent shows antifungal activity and is effective in moderate to severe dandruff. However, it may not be acceptable to all patients as it may increase sebum production. Side effects of the use of selenium include orange staining of the scalp and lightening of hair colour.[2] It is therefore advisable to avoid use 48 hours before and after hair colouring and after the use of waving or straightening agents. It should be applied twice weekly for two weeks, once a week for two weeks and then as required.

Zinc pyrithione. Zinc pyrithione shampoo, also known as ZPT, reduces the level of fungus on the scalp, which appears to be its main mode of action in treating dandruff. It should be used weekly and left in contact with the hair for five to 10 minutes.

Steroids. Steroid lotions exert their benefit through their anti-inflammatory action and have no influence on the levels of fungus on the scalp, so this could explain why use of these agents does not produce long-lasting benefit.

Coal tar and salicylic acid. Coal tar inhibits cell division, so slows down the build-up of dead skin cells. It also has antifungal and anti-inflammatory properties. Salicylic acid is keratolytic and sloughs off dead skin cells, so preventing the build-up of flakes on the scalp. There are various shampoos containing coal tar, with or without salicylic acid, and some can be used on a daily basis.

Ketoconazole. This imidazole antifungal has strong activity against *P ovale*, so may have the edge over other preparations. The 2 per cent shampoo should be used twice weekly for two to four weeks. Once the scalp is clear the shampoo can be used once every one or two weeks, with normal shampoo in between. Itching and burning may be a side effect.

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Mike Wyndham MB, BS, DRCOG, MRCGP, is a former GP trainer and now joint course organiser for Barnet Hospital Vocational Training Scheme for General Practice. He is the scheme's educational lead for dermatology.

Product news

Teen dreams

Teenagers, the main users of medicated skin care, are excited by innovation so retailers should concentrate on promoting new products, says GlaxoSmithKline. New sectors are driving value growth in this sector, with wipes performing particularly well. Recent launches have focused on novelty delivery systems and make-up containing salicylic acid, which are changing the market.

Credibility among peers is important to teenagers, so advertising and packaging needs to empathise strongly with the target market. Price reductions are also a motivating factor (even though mum might be the main purchaser) and the internet is becoming increasingly important for this audience.

Washes are the biggest sector, accounting for 31 per cent of the £83 million market. Boys favour no-fuss products such as pads, which help prevent spots, whereas girls are more likely to take a regime approach. Top brands are Clean & Clear, Clearasil and Oxy.

The market's increasing complexity is resulting in pressure on shelf space. The company's advice is to focus on top-selling brands backed by advertising and to ensure that all formats are displayed.

Oxy is positioned as a teenage specialist product, supported year round with cinema and press advertising and a presence on the internet. The last cinema campaign featured a boy whose attempts to chat up girls were frustrated by an animated spot.

Skin flare-up

One in five UK adults (about 12 million) suffer from skin flare-up, described as patches of itchy, red skin caused by excessive reaction of the immune system to triggers such as detergents, perfumes and solvents. Stress triggers for eczema are also on the increase.

GlaxoSmithKline says skin flare-up is the fastest growing healthcare category, worth about £60m. Most people (90-95 per cent) are driven to treat the condition because of the irritating itch. Sufferers experience three or four episodes a year, lasting an average 28 days. They frequently ask pharmacists for advice before consulting a GP, which puts pharmacists in an ideal position to recommend an effective step down regime of topical steroid followed by emollients once the skin is cleared.

Cold sore deceptors

There are millions of cold sore sufferers, according to GlaxoSmithKline. Frettors tend to be more concerned with how they look and are more likely to take action to reduce or conceal the cold sores. Acceptors are usually in a relationship and/or older and less concerned with their appearance, knowing that the cold sore will go away eventually.

Pharmacists can be important in educating sufferers that cold sores are viral and can be treated at the blister stage as well as the initial 'tingle' stage. Some people still believe that cold sores are untreatable, so often settle for soothing, disinfecting or concealing products instead of an antiviral agent. Empathy with customers, who might be feeling very embarrassed about their blemishes, should not be underestimated.

Aciclovir dominates the £25m cold sore market, which is benefiting from a general trend towards self-medication. Latest research shows that nearly two thirds of sufferers use their local pharmacy as first port of call, although this could change if the P to GSL switch application for Zovirax is successful.

A recent trial has shown that Exorex 1 per cent prepared coal tar lotion was more effective than Alphosyl 5 per cent conventional tar lotion (now withdrawn) in treating mild to moderate chronic plaque psoriasis. The trial, accepted for publication in a dermatology journal but not yet published, was a double-blind, randomised, multicentre study involving 228 patients who received 12 weeks' treatment.

The lotion is the 'treatment' element of the Exorex three-step management system, which also includes hair and body shampoo and moisturisers.

Alphosyl 2 in 1 shampoo is still available, containing 5 per cent alcoholic extract of coal tar, herbal fragrance and conditioner.

Johnson & Johnson Consumer Pharmaceuticals is supporting Nizoral anti-dandruff shampoo with a media campaign highlighting that the product is odourless and fragrance free. It contains none of the 26 fragrances, plant extracts or essential oils listed in the *Cosmetics Directive (2003/15/EC)* as potentially triggering contact allergies in sensitive individuals.

Weleda's Dermatodoron is promoted as an alternative to topical steroids for long-term eczema treatment, particularly mild eczema in children. The licensed anthroposophic medicine is also used alongside conventional prescribed treatments for daily management between flare-ups. Active principles are silicic acid and saponins from the plants Bittersweet and Lysimachia, which have anti-inflammatory properties.

Dermatodoron is on offer, six for five, until the end of August, in time for National Eczema Week from September 20-26.

Fusidic acid alternative

Staphylococcus aureus has been implicated in the exacerbation of eczema and is one of two bacteria causing impetigo. A standard treatment is topical fusidic acid, but there has been concern over the growing incidence of *S aureus* strains resistant to this antibiotic. As a result, microbiologists have called for restrictions in the use of topical fusidic acid for short-term treatment of flare-ups, to safeguard its future efficacy.

GP Pharma is recommending Crystacide, a 1 per cent hydrogen peroxide cream, as an alternative to fusidic acid in treating common skin infections. The company says there is no evidence of resistance or contact dermatitis resulting from its use. A Pharmacy medicine, Crystacide has prolonged activity – the active hydrogen peroxide molecules are embedded in a controlled release matrix of lipid crystals.

Feet facts

A recent survey by Scholl found that 23 per cent of those questioned currently had, or have had, a verruca while 24 per cent had, or have had, athlete's foot. The company is producing a new customer leaflet on treatment and prevention of foot conditions. It should be available later this summer.

To celebrate 100 years in footcare, Scholl is introducing a new brand identity and pack design, which communicate better the key product benefits to help customer decision-making at point of sale.

Crawford Healthcare has launched a new awareness campaign for Cuplex Gel. Literature for pharmacists gives advice on warts and verrucae, while for patients there is a foot-shaped information guide that can be displayed in a free dispenser.

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Clockwise from top left: Dr Soraya Dhillon, Nathalie Edenborough, Peter Weissberg and Hamish Meldrum

Soraya Dhillon has been appointed head of the University of Hertfordshire's new School of Pharmacy. The university hopes to admit pharmacy undergraduates from September 2005. Dr Dhillon is currently director of taught postgraduate studies at the University of London's School of Pharmacy, Luton and Dunstable NHS Trust chairman and Bedfordshire and Hertfordshire NHS Workforce Development Confederation chairman.

Photo and telecoms distributor Swains has expanded its sales team with the appointment of **Nathalie Edenborough** as regional sales manager for the Midlands. Most recently a sales support representative for insurance company Standard Life, Ms Edenborough's responsibilities at Swains include generating new accounts and working with existing customers.

Sinclair Pharmaceuticals has announced the appointment of **Grahame Cook** as a non-executive director. Mr Cook has over 18 years' experience in investment banking and joins Sinclair from stockbroker firm West LB Panmure where he was global chief executive officer.

Hamish Meldrum has been elected to lead the UK's 45,000 GPs as chairman of the British Medical Association's General Practitioners Committee. Dr Meldrum is a GP practising in Bridlington, East Yorkshire and has been joint deputy chairman of the GPC since 1999. He succeeds Dr John Chisholm who has stood down from the chairmanship after seven years.

The British Heart Foundation has announced that **Peter Weissberg** will be medical director from next January. Professor Weissberg is the BHF's professor of cardiovascular medicine at Cambridge University and an honorary consultant cardiologist at Addenbrooke's and Papworth hospitals. He succeeds **Professor Sir Charles George**, who was recently appointed BMA president.

Colin, whaur's yer troosers?

Traditionally, an employee completing 25 years' service is presented with a gold watch. Not so at *C&D*.

Colin Simpson has just celebrated 25 happy years working on the *C&D Price List*, contender for the most useful book in community pharmacy. But rather than receiving the usual timepiece his wife Anne suggested something he might like more: a kilt.

Despite colonial beginnings, Colin has a proud Celtic ancestry and is a qualified Scottish dance instructor. Anne's suggestion won the support of our publishing director and board director, both Scots themselves.

As a kilt is not victim to the vagaries of the ups and downs of hemlines in the fashion world, Colin's wife Anne had to use a bit of cunning to measure Colin's hip to knee length. Well, actually a piece of string. Several months on Colin has been presented with the kilt and a shiny new buckle.

And afore ye ask, Colin claims descent from the Fraser clan and the tartan is described as Fraser Hunting Old Colours: its muted tones make it more suitable for stalking ptarmigan on the brae than some more garish tartans.

Colin has yet to wear the kilt to the office, no doubt as he will get sick of every Sassenach's question on seeing it: "Is it true that a haggis has three legs?"

Toothpaste fights plaque, decay and shingles

Suffering with piles? Or shingles? Toothpaste may be the answer, if readers of the *Sunday Telegraph* are to be believed.

In his medical column last week, Dr James Le Fanu followed the success story of a man who applied Colgate toothpaste instead of his usual cream to his haemorrhoids, with a shingles sufferer's account of her unconventional use of a Sensodyne product.

Mary Sillett decided to apply a thin layer of the toothpaste to her shoulder and arm, in which she suffered a "red-hot needle sensation" and found it remarkably effective. Her family doctor, though surprised, has promised to pass on the tip to other shingles sufferers but, as it is a blacklisted product, will be unable to prescribe it for the foreseeable future.

Anyone wishing to emulate the ...ions of Dr Le Fanu's readers ...ed to give serious thought as ... parts of their bodies they ...ed 'minty fresh', as this ... to be an unusual yet ... de effect of such ...

Young, (diet) free and single

Current economic theories on dieting (yes, they do actually exist) have suggested that single people are more likely to diet than those who are married. This has been put down to singles wanting to boost their chances of finding a partner.

But this theory has been challenged by some recent research. An economics post-graduate student at Warwick University has found that while 41.5 per cent of married women are dieting, only 29 per cent of single women are trying to lose weight. Reasons given for this include women dieting to encourage their partner to lose weight, or married women dieting in preparation for a separation and the need to find a new partner.

And the traditional theory of women being obsessed with how they look while men are not bothered has also been challenged by the study. The 34 per cent increase from 1980 to 1999 in the number of women dieting was accompanied by a 22 per cent rise in the number of men.

Stop sniggering at the back ... oh, go on then

There are few pleasures left in life so we must make the most of the gems that come our way.

The plethora of pharmacy and NHS acronyms readily induces deep sedation, but the acronym for the Council for the Regulation of Healthcare Professionals did provide some welcome relief.

I say did, because CRHP (pronounced CHiRP and not CRaHP) is no more: the organisation has decreed that to avoid "possible confusion with bodies of a similar name" it is re-branding itself as the Council for Healthcare Regulatory Excellence or CRHE for short.

As Jim Royle of TV's Royle family might have said: "CRHE my arse."

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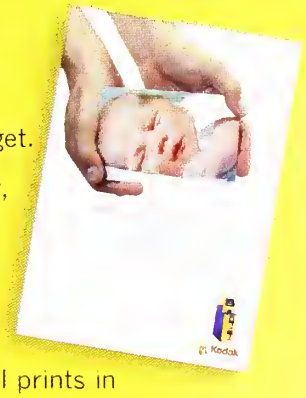

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